

Title of Research Study: "Protect Against Heart Attack & Stroke: Know Your Numbers to Control Your Risk"

Revision 1: 6/22/22

Revision 2: 7/21/22

Investigator Team Contact Information:

For questions about research appointments, the research study, research results, or other concerns, call the study team at:

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Key Information About This Research Study

The following is a short summary to help you decide whether or not to be a part of this research study. More detailed information is listed later on in this form.

This is a community survey. During the course of this study, we will ask you questions about your own medical perceptions, medical history, and personal demographics. We will also take a blood sample to assess your cholesterol levels (unless you have a recent cholesterol value from your provider - in which case we will skip the blood sample), assess your height, weight, body composition, and blood pressure. We will be doing heart attack and stroke education. Personalized risk scores for heart attack and stroke will be calculated as a part of this study, though some scores may not be available to all participants depending on variations in past medical history.

What is research?

- The goal of research is to learn new things in order to help people in the future. Investigators learn things by following the same plan with a number of participants, so they do not usually make changes to the plan for individual research participants. You, as an individual, may or may not be helped by volunteering for a research study.

Why am I being invited to take part in this research study?

We are asking you to take part in this research study because it helps us to better understand the public health of our community as it relates to stroke and heart attack risk. Individually, the participant will benefit from personalized education.

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Why is this research being done?

We are conducting this study so that we can better understand heart attack and stroke risk in humans. This is also an excellent time to educate our community members.

How long will the research last?

We expect that you will be in this research study for roughly 20 minutes

What will I need to do to participate?

You will be asked to complete survey questions, potentially provide a blood sample, have your blood pressure taken, help to collect your height, weight, and participate in education.

More detailed information about the study procedures can be found under “What happens if I say yes, I want to be in this research?”

Is there any way that being in this study could be bad for me?

There are some risks to this study, but we have worked hard to keep those risks low. The main risks are infection related to finger-prick if we need to assess your cholesterol values, unwanted and/or misinterpreted lab results, and bodily injury (because of the blood pressure cuff).

More detailed information about the risks of this study can be found under **“What are the risks of this study? Is there any way being in this study could be bad for me? (Detailed Risks)”**

Will being in this study help me in any way?

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include personal education, increased knowledge, and prize incentive.

More detailed information about the benefits of this study can be found under **“Will being in this study help me in any way?”**

What happens if I do not want to be in this research?

There are no known alternatives, other than deciding not to participate in this research study.

Your decision whether or not to participate will not affect your current or future relationships with the University of Minnesota. If you decide to participate, you are free to not answer any question or withdraw at any time without affecting those relationships.

Detailed Information About This Research Study

The following is more detailed information about this study in addition to the information listed above.

How many people will be studied?

We expect about 300 people here will be in this research study out of 300 people in the entire study nationally.

What happens if I say “Yes, I want to be in this research”?

The following events will take place with these general guidelines in mind. Our study volunteers (nursing students) and/or study coordinators will assist you throughout the study. This will take about 20 minutes and will all be completed right here at the State Fair. We will not need to reach you after the below events are completed. No audio or visual recordings are needed nor permitted. Reference materials for study questions can be made available upon request.

- Our study volunteers will help you complete your survey on the iPad. You will walk through a personal information and consent section, a demographic information section (including race, ethnicity, education, income, etc.) and a brief health history section around various elements of your past medical and health history, including but not limited to smoking, cardiovascular disease, exercise, and health perception.
- We will weigh you and take your height as well as body composition

- We may clean and prick your finger for a blood cholesterol sample (note, your cholesterol values will be taken here at the fair unless you are able to provide a recent lab value from a medical visit within the past year)
- We will take your blood pressure
- We will calculate some data and give you your risk score for the likelihood (risk) of you having a heart attack in 10 years and the likelihood (risk) of you having a stroke within 10 years. Note that people with prior medical history of stroke are not eligible to receive a stroke risk score due to limitations in the calculations
- We will educate you on heart attacks, stroke, and general health
- We will reassess health perception
- You will be allowed one prize incentive for participating

That will be the end of your involvement in the study.

What happens if I say “Yes”, but I change my mind later?

You can leave the research study at any time and no one will be upset by your decision.

What are the risks of being in this study? Is there any way being in this study could be bad for me? (Detailed Risks)

- Physical risks: We may be pricking your finger for a blood sample. While we will be cleansing the finger thoroughly, there is always a small risk of infection. There is also a risk of minimal to severe physical harm should blood pressure be taken on an arm that cannot sustain a blood pressure. This risk is rare. Furthermore, we will check all participants using a screening to ensure we can safely take your blood pressure.
- Psychological risks: You may receive a blood pressure reading, heart attack risk score, stroke risk score, cholesterol value, or any other lab data point or study point that may commonly induce anxiety. Know that this risk is minimal and we will be providing education to all participants. There is also a known risk that your lab result (blood pressure and/or cholesterol value) may come back with emergency-level values. While extremely unlikely, the study coordinators can help you get emergency care if this situation arises. The State Fair has [First Aid](#) available at all times during the study, and more advanced care is available 24/7 through EMS.
- Privacy and confidentiality risks: There is some risk of a data breach involving the information we have about you. We comply with the University’s security standards to secure your information and minimize risks, but there is always a possibility of a data breach.
- Social risks: It is important to know that this is a research study. We, as nurses, are not diagnosing you with any medical condition. We will be providing you with education and can teach you about heart attack, stroke, different medical providers (care coordination), etc.

In addition to these risks, this research may hurt you in ways that are unknown. These might be minor or be severe enough to cause death.

Will it cost me anything to participate in this research study?

- There will be no cost to you for any of the study activities or procedures.

Will being in this study help me in any way? (Detailed Benefits)

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include personal education, societal education, helping out your community, increased personal and holistic knowledge, and a prize incentive.

What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete confidentiality.

Organizations that may inspect and copy your information include the Institutional Review Board (IRB), the committee that provides ethical and regulatory oversight of research, and other representatives of this institution, including those that have responsibilities for monitoring or ensuring compliance.

We may publish the results of this research. However, we will keep your name and other identifying information confidential.

Will I receive research test results?

We will give you all of your results per above. However, should the investigators stumble upon a medical emergency during the course of the study, we will help you get the care that you need. Again, first aid is available at all times during the study (see above).

Most tests done on samples in research studies are only for research and have no clear meaning for health care.

What will be done with my data when this study is over?

Your data and/or samples will not be used for any future research after this study is complete.

Whom do I contact if I have questions, concerns or feedback about my experience?

This research has been reviewed and approved by an IRB within the Human Research Protections Program (HRPP). To share feedback privately with the HRPP about your research experience, call the Research Participants' Advocate Line at 612-625-1650 (Toll Free: 1-888-224-8636) or go to z.umn.edu/participants. You are encouraged to contact the HRPP if:

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

Will I have a chance to provide feedback after the study is over?

The HRPP may ask you to complete a survey that asks about your experience as a research participant. You do not have to complete the survey if you do not want to. If you do choose to complete the survey, your responses will be anonymous.

If you are not asked to complete a survey, but you would like to share feedback, please contact the study team or the HRPP. See the "Investigator Contact Information" of this form for study team contact information and "Whom do I contact if I have questions, concerns or feedback about my experience?" of this form for HRPP contact information.

Can I be removed from the research?

The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include [cases of extreme data points that would otherwise compromise study results](#).

We will tell you about any new information that may affect your health, welfare, or choice to stay in the research.

What happens if I am injured while participating in this research?

In the event that this research activity results in an injury, treatment will be available, including first aid, emergency treatment and follow-up care as needed. Care for such injuries will be billed in the ordinary manner, to you or your insurance company. If you think that you have suffered a research related injury let the study coordinators know right away.

Will I be compensated for my participation?

If you agree to take part in this research study, we will offer you one wheel-spin to collect a prize (prizes have varying values)

Military personnel should check with their supervisor before accepting payment for participation in this research.

Use of Identifiable Health Information

We are committed to respect your privacy and to keep your personal information confidential. When choosing to take part in this study, you are giving us the permission to use your personal health information that includes health information in your medical records and information that can identify you. Those persons who get your health information may not be required by Federal privacy laws (such as the 1099 Rule) to protect it. Some of those persons may be able to share your information with others without your separate permission. Please read the HIPAA Authorization form that we have provided and discussed.

The results of this study may also be used for teaching, publications, or for presentation at scientific meetings.

Your signature documents your permission to take part in this research. You will be provided a copy of this signed document.

Signature of Participant

Date

Printed Name of Participant

Signature of Person Obtaining Consent

Date

Printed Name of Person Obtaining Consent