

**Vanderbilt University Institutional Review Board
Informed Consent Document for Research**

Principal Investigator: C. Michael Stein, MBChB

Version Date: 10/28/21

Study Title: Inflammatory and Vascular Response to Dietary Salt in Rheumatoid Arthritis

Institution/Hospital: Vanderbilt University

This informed consent applies to adults with RA.

Name of participant: _____ Age: _____

The following is given to you to tell you about this research study. Please read this form with care and ask any questions you may have about this study. Your questions will be answered. Also, you will be given a copy of this consent form.

You do not have to be in this research study. You can stop being in this study at any time. If we learn something new that may affect the risks or benefits of this study, you will be told so that you can decide whether or not you still want to be in this study. Your medical record will contain a note saying you are in a research study. Anyone you authorize to receive your medical record will also get this note.

1. What is the purpose of this study?

You are being asked to take part in this research study because you have rheumatoid arthritis (RA.) Studies have shown that people with RA have a higher rate of high blood pressure than people who don't have RA. We believe this is caused by the inflammation produced by RA. We want to study whether changing the amount of salt in the diet affects certain measures of inflammation in the blood that may be linked to an increase in blood pressure. We hope that by studying these changes, we will learn how to better treat people with RA. About 50 people will take part in this study.

2. What will happen and how long will you be in the study?

If you agree to be in the study, we will meet to discuss your medical history either in person or by phone or virtual meeting. If you qualify for the study, you will come to Vanderbilt. We will do a physical exam and ask you about your medical history. We will also look at your medical record to get information about you. We will ask you to complete a short questionnaire. You will speak with a dietician who will explain the diet and plan your meals. You will choose 14 meals low in salt (lunch and dinner for 7 days) from a selection provided by a company that will deliver them to your house in a cooler. You will need to keep the meals in a refrigerator. The dietician will tell you what you can have for breakfast and snacks that you can eat and drink while on the diet. We will provide a low-salt breakfast cereal for you. During the high-salt diet you will choose 14 meals higher in salt, and we will also provide you with cereals, snacks, and drinks that are higher in salt and packets of salt to put on your food. You must not eat or drink anything other than what the dietician says you can.

If you have not had blood tests in the last 3 months we will take blood from your arm using a needle (about 1 ½ teaspoons) to check that it is safe for you to be in the study. If you are a woman who could become pregnant, you will have a urine pregnancy test. If you are pregnant, you will not be allowed to be in the study.

We will teach you to use a 24-hour blood pressure monitor.

We will give you a different machine to take your blood pressure once a week at home. During the high-salt and low-salt diets, we will ask you to take your blood pressure at home once a week after you have sat and rested quietly for at least 5 minutes. We will ask you to contact us if the top number is more than 160 or the bottom number is more than 100. You will keep this machine at home until the end of the study and then return it to us.

We will ask you to weigh yourself once a week at home and tell the study staff your weight each week.

Your samples and information about you may be made available to others to use for research. To protect your privacy, we will not release your name. You will not receive any benefit as a result of the tests done on you

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samples. These tests may help us learn more about the causes, risks, treatments of RA and high blood pressure, or how to prevent these and other health problems.

Your samples may be used to make new products or tests. These may have value and may be developed and owned by the study staff, Vanderbilt University, and/or others. If this happens, there are no plans to provide money to you.

Study Day 1

If your labwork results are satisfactory, we will ask you to come back to Vanderbilt for Study Day 1. The day before the study day we will ask you to collect all the urine you produce for 24 hours in a jug that we will give to you and bring it with you when you come to the visit. We will ask you to collect a stool sample using a kit we will give you and bring the sample with you to the study visit.

The day before the study day we will ask you to wear the 24-hour blood pressure monitor and to keep an activity diary. This will measure your blood pressure every 15-30 minutes during the day and every 30 minutes at night for the next 24 hours. You will wear this for 24 hours. When the machine takes your blood pressure, the cuff will get tight around your arm. If it is so tight that it feels painful, you can push the button to stop the measurement. The cuff will go down and release the pressure on your arm. If the arm gets swollen, numb, or bruised you should stop the readings and take the cuff off. We will ask you to bring the monitor to your visit. If you are not able to put the monitor on yourself or if it does not work properly we will put it on for you on at the end of your study visit. After it has run for 24 hours we will ask you to return the monitor and activity diary to us either by dropping them off or sending them in a prepaid box.

We will ask you not to have anything to eat or drink, except water, for 6 hours before this visit. We will ask that you not brush or floss your teeth after midnight the day before the study day.

When you arrive, we will ask you for a urine sample. If you are a woman who could become pregnant, you will have a urine pregnancy test. We will ask you to spit into a bottle and complete a short questionnaire. We will take blood from your arm with a needle (about 4.5 tablespoons). We will also give you a brief physical exam.

We will ask you to lie down for 10 minutes. We will then measure your blood pressure. We will also measure your blood flow using a device called a tonometer that we will hold lightly against your skin at the point your arteries are closest to the skin in your arm, neck, and leg.

We will place a blood pressure cuff on one arm and small probes on one finger on each of your hands. We will place soft sponge rings on either side of the probed fingers to keep them separated. The probes will measure the blood flow in your fingers. It is not invasive and does not cause pain.

After 5-10 minutes, we will inflate the blood pressure cuff 60 points above the highest number on your normal blood pressure. The cuff will stay inflated for 5 minutes. We will then let the air out of the cuff and again measure the blood flow in your fingers.

You will then be finished with Study Day 1.

Study Day 2

For eight weeks before Study Day 2, you will eat a special diet. You will either have a high-salt diet or a low-salt diet. You and the dietician will know which diet you are on, but you should not tell other study personnel which diet you are on. The dietician will communicate with you ever 1-2 weeks to talk about your diet.

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The day before the study day we will ask you to wear the 24-hour blood pressure monitor and to keep an activity diary. This will measure your blood pressure every 15-30 minutes during the day and every 30 minutes at night for the next 24 hours. You will wear this for 24 hours. When the machine takes your blood pressure, the cuff will get tight around your arm. If it is so tight that it feels painful, you can push the button to stop the measurement. The cuff will go down and release the pressure on your arm. If the arm gets swollen, numb, or bruised you should stop the readings and take the cuff off. We will ask you to bring the monitor to your visit. If you are not able to put the monitor on yourself or if it does not work properly we will put it on for you on at the end of your study visit. After it has run for 24 hours we will ask you to return the monitor and activity diary to us either by dropping them off or sending them in a prepaid box.

We will ask you not to have anything to eat or drink, except water, for 6 hours before this visit. We will ask that you not brush or floss your teeth after midnight the day before the study day.

When you arrive, we will ask you for a urine sample. If you are a woman who could become pregnant, you will have a urine pregnancy test. We will ask you to spit into a bottle and complete a short questionnaire. We will take blood from your arm with a needle (about 4.5 tablespoons). We will also give you a brief physical exam.

We will ask you to lie down for 10 minutes. We will then measure your blood pressure. We will also measure your blood flow using a device called a tonometer that we will hold lightly against your skin at the point your arteries are closest to the skin in your arm, neck, and leg.

We will place a blood pressure cuff on one arm and small probes on one finger on each of your hands. We will place soft sponge rings on either side of the probed fingers to keep them separated. The probes will measure your blood pressure. It is not invasive and does not cause pain.

After 5-10 minutes, we will inflate the blood pressure cuff 60 points above the highest number on your normal blood pressure. The cuff will stay inflated for 5 minutes. We will then let the air out of the cuff and again measure the blood flow in your fingers.

We will ask you to have a magnetic resonance imaging (MRI) scan.

The MRI scan will take about 45 minutes. An MRI scan is taken in a large machine that is shaped like a tunnel. This scan does not use X-rays. Instead, they use a strong magnet and radio waves, like those used in an AM/FM radio to make pictures of your body.

You may not be able to have this scan if you have a device in your body such as aneurysm clips in the brain, heart pacemakers or defibrillators, and cochlear implants. Also, you may not be able to have this scan if you have iron-based tattoos or pieces of metal (bullet, BB, shrapnel) close to or in an important organ (such as the eye).

Certain metal objects like watches, credit cards, hairpins, writing pens, etc. may be damaged by the machine or may be pulled away from the body when you are getting the scan. Also, metal can sometimes cause poor pictures if it is close to the part of the body being scanned. For these reasons, you will be asked to remove these objects before going into the room for the scan.

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You will hear “hammering”, clicking, or squealing noises during the scan. You will be given earplugs to reduce the noise. You will also be told how to alert the staff if you need them.

During the scan, the MRI staff is able to hear and talk to you. You will also be able to hear the staff. They will be talking to you during your scan and may ask you to hold your breath, not move, or other simple tasks. You will be asked to lie very still throughout the scan.

You will then be finished with Study Day 2.

Study Day 3

For four weeks before Study Day 3, you may eat your regular diet.

The day before the study day 3 we will ask you to collect all the urine you produce for 24 hours in a jug that we will give to you and bring it with you when you come to the visit. We will ask you to collect a stool sample using a kit we will give you and bring the sample with you to the study visit.

The day before the study day we will ask you to wear the 24-hour blood pressure monitor and to keep an activity diary. This will measure your blood pressure every 15-30 minutes during the day and every 30 minutes at night for the next 24 hours. You will wear this for 24 hours. When the machine takes your blood pressure, the cuff will get tight around your arm. If it is so tight that it feels painful, you can push the button to stop the measurement. The cuff will go down and release the pressure on your arm. If the arm gets swollen, numb, or bruised you should stop the readings and take the cuff off. We will ask you to bring the monitor to your visit. If you are not able to put the monitor on yourself or if it does not work properly we will put it on for you on at the end of your study visit. After it has run for 24 hours we will ask you to return the monitor and activity diary to us either by dropping them off or sending them in a prepaid box.

We will ask you not to have anything to eat or drink, except water, for 6 hours before this visit. We will ask that you not brush or floss your teeth after midnight the day before the study day.

When you arrive, we will ask you for a urine sample. If you are a woman who could become pregnant, you will have a urine pregnancy test. We will ask you to spit into a bottle and complete a short questionnaire. We will take blood from your arm with a needle (about 4.5 tablespoons). We will also give you a brief physical exam.

We will ask you to lie down for 5-10 minutes. We will then measure your blood pressure. We will also measure your blood flow using a device called a tonometer that we will hold lightly against your skin at the point your arteries are closest to the skin in your arm, neck, and leg.

We will place a blood pressure cuff on one arm and small probes on one finger on each of your hands. We will place soft sponge rings on either side of the probed fingers to keep them separated. The probes will measure your blood pressure. It is not invasive and does not cause pain. After 10 minutes, we will inflate the blood pressure cuff 60 points above the highest number on your normal blood pressure. The cuff will stay inflated for 5 minutes. We will then let the air out of the cuff and again measure the blood flow in your fingers.

You will then be finished with Study Day 3.

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Study Day 4

For eight week before Study Day 4 you will eat a special diet. You will either have a high-salt diet or a low-salt diet, whichever you did not get before Study Day 2. You and the dietician will know which diet you are on but you should not tell other study personnel which diet you are on. The dietician will communicate with you every 1-2 weeks to talk about your diet.

The day before the study day 4 we will ask you to collect all the urine you produce for 24 hours in a jug that we will give to you and bring it with you when you come to the visit. We will ask you to collect a stool sample using a kit we will give you and bring the sample with you to the study visit.

The day before the study day we will ask you to wear the 24-hour blood pressure monitor and to keep an activity diary. This will measure your blood pressure every 15-30 minutes during the day and every 30 minutes at night for the next 24 hours. You will wear this for 24 hours. When the machine takes your blood pressure, the cuff will get tight around your arm. If it is so tight that it feels painful, you can push the button to stop the measurement. The cuff will go down and release the pressure on your arm. If the arm gets swollen, numb, or bruised you should stop the readings and take the cuff off. We will ask you to bring the monitor to your visit. If you are not able to put the monitor on yourself or if it does not work properly we will put it on for you on at the end of your study visit. After it has run for 24 hours we will ask you to return the monitor and activity diary to us either by dropping them off or sending them in a prepaid box.

We will ask you not to have anything to eat or drink, except water, for 6 hours before this visit. We will ask that you not brush or floss your teeth after midnight the day before the study day.

When you arrive, we will ask you for a urine sample. If you are a woman who could become pregnant, you will have a urine pregnancy test. We will ask you to spit into a bottle and complete a short questionnaire. We will take blood from your arm with a needle (about 4.5 tablespoons). We will also give you a brief physical exam.

We will ask you to lie down for 10 minutes. We will then measure your blood pressure. We will also measure your blood flow using a device called a tonometer that we will hold lightly against your skin at the point your arteries are closest to the skin in your arm, neck, and leg.

We will place a blood pressure cuff on one arm and small probes on one finger on each of your hands. We will place soft sponge rings on either side of the probed fingers to keep them separated. The probes will measure the blood flow in your fingers. It is not invasive and does not cause pain.

After 10 minutes, we will inflate the blood pressure cuff 60 points above the highest number on your normal blood pressure. The cuff will stay inflated for 5 minutes. We will then let the air out of the cuff and again measure the blood flow in your fingers.

We will ask you to have a magnetic resonance imaging (MRI) scan. MRIs are often performed to obtain pictures of organs in clinical practice.

The MRI scan will take about 45 minutes. An MRI scan is taken in a large machine that is shaped like a tunnel. This scan does not use X-rays. Instead, they use a strong magnet and radio waves, like those used in an AM/FM radio to make pictures of your body.

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You may not be able to have this scan if you have a device in your body such as aneurysm clips in the brain, heart pacemakers or defibrillators, and cochlear implants. Also, you may not be able to have this scan if you have iron-based tattoos or pieces of metal (bullet, BB, shrapnel) close to or in an important organ (such as the eye).

Certain metal objects like watches, credit cards, hairpins, writing pens, etc. may be damaged by the machine or may be pulled away from the body when you are getting the scan. Also, metal can sometimes cause poor pictures if it is close to the part of the body being scanned. For these reasons, you will be asked to remove these objects before going into the room for the scan.

You will hear "hammering", clicking, or squealing noises during the scan. You will be given earplugs to reduce the noise. You will also be told how to alert the staff if you need them.

During the scan, the MRI staff is able to hear and talk to you. You will also be able to hear the staff. They will be talking to you during your scan and may ask you to hold your breath, not move, or other simple tasks. You will be asked to lie very still throughout the scan.

You will then be finished with the study.

If you are unable to complete the study for logistical reasons, you may re-enroll at a later time so long as you still meet the study requirements.;

3. Costs to you if you take part in this study:

There is no cost to you for taking part in this study.

4. Side effects and risks that you can expect if you take part in this study:

Coming to Vanderbilt for study days may be inconvenient.

Blood pressure measurements – Wearing a blood pressure meter for 24 hours may be inconvenient and may interrupt your sleep. Writing down your activities may be inconvenient.

Blood draws - Pain, redness, soreness, bruising, or rarely infection may occur at the needle stick site. Rarely some people faint.

Urine collection – Collecting your urine for 24 hours several times may be inconvenient.

Stool collection – Collecting your stool the day before your 4 study visits may be inconvenient.

Diet – Eating a special diet may be inconvenient. The food may not taste good. A high-salt diet may increase blood pressure in some people.

You may feel hungry or lose weight eating the prepared diets. If this happens, the dietitians will work with you and tell you what foods you can prepare at home to supplement the prepared meals.

MRI

There are no known major risks with an MRI scan. But, it is possible that harmful effects could be found out in the future. Even though the tunnel is open, it may bother you to be placed in a tight space (claustrophobia), and

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to hear the noise made by the magnet during the scan. You will be given earplugs to reduce the noise. You may also feel the table vibrate and/or move slightly during the scan. It may be hard to lie on the table during the scan. If you have any metal pieces in your body, they could move during the scan and damage nearby tissues or organs.

If you use a transdermal patch (medicated patches applied to the skin), you will need to take it off during the MRI scan. Some patches have metal in the layer of the patch that is not in contact with the skin (the backing). You may not be able to see the metal in the backing of these patches. Patches that contain metal can overheat during an MRI scan and cause skin burns in the immediate area of the patch. Tell the study doctor that you are using a patch and why you are using it (such as, for pain, smoking cessation, hormones). Ask your doctor for guidance about removing and disposing of the patch before having an MRI scan and replacing it after the procedure. Tell the MRI facility that you are using a patch. You should do this when making your appointment and during the health history questions you are asked when you arrive for your appointment.

There are no known risks of having MRI scans without contrast while pregnant. However, there may be risks that are unknown.

5. Risks that are not known:

None.

6. Payment in case you are injured because of this research study:

If it is determined by Vanderbilt and the Investigator that an injury occurred as a direct result of the tests or treatments that are done for research, then you and/or your insurance will not have to pay for the cost of immediate medical care provided **at Vanderbilt** to treat the injury.

There are no plans for Vanderbilt to pay for the costs of any additional care. There are no plans for Vanderbilt to give you money for the injury.

7. Good effects that might result from this study:

a) The benefits to science and humankind that might result from this study. We may learn more about why people with certain autoimmune diseases have higher rates of heart disease.

b) The benefits you might get from being in this study. None

8. Other treatments you could get if you decide not to be in this study:

This is not a treatment study. You may decide not to be in this study and nothing about your healthcare will change.

9. Payments for your time spent taking part in this study or expenses:

If you complete the study, you will be paid \$1,000. If you do not complete the study, you will be paid as follows:
\$250 per study day completed

If you travel more than 10 miles for visits, we will reimburse you for mileage at the current federal rate.

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We may ask you for your Social Security number and address before you are compensated for taking part in this study.

You may receive up to \$1,000 for taking part in this study. This amount may be taxable and will be reported to the Internal Revenue Service (IRS).

10. Reasons why the study doctor may take you out of this study:

You may be removed from this study without your consent if:

- Staying in the study would be harmful to you
- You no longer meet the requirements of the study
- The study is stopped.

If you are taken out of the study, you will be told the reason.

11. What will happen if you decide to stop being in this study?

If you decide to stop being part of the study, you should tell your study doctor.

12. Who to call for any questions or in case you are injured:

If you should have any questions about this research study or if you feel you have been hurt by being a part of this study, please feel free to contact Dr. Michael Stein's office at 615-936-3420. If you cannot reach the research staff, please call or text Dr. Stein at 615-957-2523.

For additional information about giving consent or your rights as a person in this study, to discuss problems, concerns, and questions, or to offer input, please feel free to call the Vanderbilt University Institutional Review Board Office at (615) 322-2918 or toll free at (866) 224-8273.

13. Clinical Trials Registry.

A description of this clinical trial will be available on 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.

14. Confidentiality:

Information we collect from you will be stored in a secure, password-protected database. Your samples will be labeled with a code instead of your name. Access to this information will be granted only to members of the study team.

Dr. Stein and/or Vanderbilt may share your information and/or samples, without identifiers, to others or use it for other research projects not listed in this form. Vanderbilt, Dr Stein and his staff will comply with any and all laws regarding the privacy of such information. There are no plans to pay you for the use or transfer of this de-identified information or samples.

This study may have some support from the National Institutes of Health (NIH). If so, your study information is protected by a Certificate of Confidentiality. This Certificate allows us, in some cases, to refuse to give out your information even if requested using legal means.

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It does not protect information that we have to report by law, such as child abuse or some infectious diseases. The Certificate does not prevent us from disclosing your information if we learn of possible harm to yourself or others, or if you need medical help.

Disclosures that you consent to in this document are not protected. This includes putting research data in the medical record or sharing research data for this study or future research. Disclosures that you make yourself are also not protected.

15. Authorization to Use/Disclose Protected Health Information

All efforts, within reason, will be made to keep your protected health information (PHI) private. PHI is your health information that is, or has been gathered or kept by Vanderbilt as a result of your healthcare. This includes data gathered for research studies that can be traced back to you. Using or sharing ("disclosure") such data must follow federal privacy rules. By signing the consent for this study, you are agreeing ("authorization") to the uses and likely sharing of your PHI. If you decide to be in this research study, you are also agreeing to let the study team use and share your PHI as described below.

As part of the study, Dr Stein and his study team may share the results of your study and/or non-study linked blood testing, as well as parts of your medical record, to the groups named below. These groups may include people from the Federal Government Office for Human Research Protections and the Vanderbilt University Institutional Review Board. Federal privacy rules may not apply to these groups; they have their own rules and codes to assure that all efforts, within reason, will be made to keep your PHI private.

The study results will be kept in your research record for at least six years after the study is finished. At that time, the research data that has not been put in your medical record will be kept for an unknown length of time. Any research data that has been put into your medical record will be kept for an unknown length of time.

Unless told otherwise, your consent to use or share your PHI does not expire. If you change your mind, we ask that you contact Dr. Stein in writing and let him know that you withdraw your consent. His mailing address is:

Dr. Michael Stein
542A Robinson Research Building
Clinical Pharmacology
Vanderbilt University
Nashville, TN 37232-6602

At that time, we will stop getting any more data about you. But, the health data we stored before you withdrew your consent may still be used for reporting and research quality.

If you decide not to take part in this research study, it will not affect your treatment, payment or enrollment in any health plans or affect your ability to get benefits. You will get a copy of this form after it is signed.

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STATEMENT BY PERSON AGREEING TO BE IN THIS STUDY

I have read this consent form and the research study has been explained to me verbally. All my questions have been answered, and I freely and voluntarily choose to take part in this study.

Date

Signature of patient/volunteer

Consent obtained by:

Date

Signature

Time

Printed Name and Title

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Consent for Genetic Research

The purpose of part of this study is to look at genes (DNA) and how they affect health and disease. Genes are the instruction manual for your body. The genes you get from your parents decide what you look like and how your body behaves. They can also tell us a person's risk for certain diseases and how they will respond to treatment.

You are being asked to give a blood sample for genetic research. What we learn about you from this sample will not be put in your health record. Your test results will not be shared with you or your doctor. No one else (like a relative, boss, or insurance company) will be given your test results. Health insurance companies and group health plans may not request your genetic information that comes from this research.

A blood sample will be taken at the same time we take the sample for your labwork, so you will not be stuck an extra time.

One risk of giving samples for this research may be the release of your name that could link you to the stored samples and/or the results of the tests run on your samples. This may cause problems with insurance or getting a job.

Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums. Employers with 15 or more employees may not use your genetic information that comes from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

To prevent this, these samples will be given a code. Only the study staff will know the code. The name that belongs to the code will be kept in a locked file or in a computer with a password. Only Dr. Stein and members of his study team will have access to your name.

Your sample will be used to make DNA that will be kept for an unknown length of time (maybe years) for future research. The sample will be destroyed when it is no longer needed.

At any time, you may ask to have your sample destroyed. You should contact Dr. Stein at
Dr. Mike Stein
542 A Robinson Research Bldg
Division of Clinical Pharmacology
Vanderbilt University
Nashville, TN 37232-6602

to have your sample destroyed and no longer used for research. We will not be able to destroy research data that has already been gathered using your sample. Also, if your identity was removed from the samples, we will not be able to locate and destroy them.

Please check Yes or No to the questions below:

My blood/tissue sample may be used for gene research.

☐ Yes ☐ No

My blood/tissue sample may be stored/shared for future gene research in heart disease.

Date of IRB Approval: 12/07/2023
Date of Expiration: 12/06/2024

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Institutional Review Board



**Vanderbilt University Institutional Review Board
Informed Consent Document for Research**

Principal Investigator: C. Michael Stein, MBChB

Version Date: 10/28/21

Study Title: Inflammatory and Vascular Response to Dietary Salt in Rheumatoid Arthritis

Institution/Hospital: Vanderbilt University

☐ Yes ☐ No

My blood/tissue sample may be stored/shared for future gene research for other health problems (such as cancer, kidney disease, etc).

☐ Yes ☐ No

Signature: _____ Date: _____

Date of IRB Approval: 12/07/2023
Date of Expiration: 12/06/2024

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Institutional Review Board

