Coronary Artery Risk Development in Young Adults (CARDIA) Ancillary Study
Informed Consent Document

Title of Research: Dietary sodium, inflammation, and salt-sensitivity of blood pressure

IRB Protocol Number: IRB-30004964

Principal Investigator: Cora E. Lewis, MD, MSPH
(205) 934-2294

Clinical Site/Location: University of Alabama at Birmingham (UAB)
Division of Preventive Medicine (DOPM) Research Clinic
1717 11th Avenue South, 7th Floor, Birmingham, AL 35205

Study Staff: Kelly Hardy
(205) 934-2024

Sponsor: National Institutes of Health (NIH)/National Heart, Lung and Blood Institute (NHLBI)/Vanderbilt University Medical Center

General Information	You are being invited to take part in a research study. This research study is voluntary, meaning you do not have to take part in it. The procedures, risks, and benefits are fully described further in the consent form.
Purpose	The purpose of the study is to assess whether dietary salt intake influences blood pressure through inflammation.
Duration & Visits	You will have one 30-minute telephone call and 4 in person clinic visits that will occur over a 1-month period, with typically one week in between each visit.
Overview of Procedures	For this ancillary study, you will have 4 study visits one of these visits may be your CARDIA year 35 core exam. At the first study visit (which may be your CARDIA year 35 core exam), your eligibility for this ancillary study will be assessed, informed consent obtained, and a brief dietary survey completed. If you consent and qualify for this study, then you will have 3 subsequent study visits during which you will have measurement of vital signs (heart rate, blood pressure, weight) and a fasting blood draw (about 2 tablespoons). In between study visits, you will eat a low-salt diet for 1 week and a high-salt diet for 1 week. On the day before each of the 3-study visits, you will collect your urine for 24 hours and wear an automated blood pressure cuff for 24 hours.
Risks	The most likely risks include pain or bruising from the blood draw, fasting, as well as low- and high-salt diets can cause low and high blood volume responses, respectively, and loss of confidentiality.
Benefits	You will not benefit from taking part in this study. The results of this research study may advance our understanding of the biologic mechanisms for salt-sensitivity of blood pressure and inform new preventative and therapeutic strategies. This could benefit patients in the future.
Alternatives	The alternative is to not participate in this study.

You are being invited to take part in a research study. This study is a multi-site study, meaning it will take place at several different locations.

What is the purpose of this study?

The purpose of the study is to assess whether dietary salt intake influences blood pressure through inflammation.

The amount of salt that a person eats is related to blood pressure. How salt intake influences blood pressure is not completely understood. Recent research suggested that too much salt may cause inflammation and other research suggests that inflammation contributes to higher blood pressure.

In this study, we will quantify the inflammatory and blood pressure response to dietary salt in CARDIA participants before and after eating the low- and high-salt diets (in random order). We will measure this response by collecting blood and urine samples, as well as a wearable 24-hour blood pressure monitoring device.

This CARDIA ancillary study will enroll approximately 500 participants at both CARDIA Centers. Approximately 250 participants at UAB, who are returning for the CARDIA Year 35 Exam, will take part in this ancillary study.

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

From the first study visit, it will take you approximately 1 month to complete this study. Details of the study timeline and procedures for each study visit are outlined below.

Screening telephone call

A telephone interview will be conducted with each potential CARDIA participant at the Birmingham field center. The interview may occur prior to the Year 35 CARDIA core exam, during the CARDIA core exam, or at a later date arranged with the participant. If they first visit is your year 35 core visit, the phone interview must take place at least 3 days prior to the year 35 core exam. During this call, the study purpose and protocol will be described with inclusion and exclusion criteria assessed. Interested participants meeting inclusion without any exclusion criteria will then be scheduled for in person CARDIA clinic visits that will occur over an approximately 1-month period, with typically one week in between each visit. You will also be randomized to one of the following dietary sequences: (1) baseline, high-salt, then low-salt diet; or (2) baseline, low-salt, then high-salt diet. Each visit will be at the CARDIA Field Center Clinic located in the UAB, DOPM Research Clinic. If you are unable to attend the in-person visits at the CARDIA Field Center Clinic, study staff may be able to arrange to drop off or pick-up of your 24 hour urine and blood pressure monitor and low-sodium meal delivery.

Enrollment Visit ("Day 0")

During this visit, we will answer any questions you have about the study, have you sign this consent form, and review your medical history, food preference questionnaire, and take your blood pressure to determine whether you qualify to take part in this research study. If you do not qualify, the study staff will tell you why. If you qualify, your schedule for subsequent study visits will be confirmed.

At this visit, we will:

- Ask about your medical history including current medication use.
- Measure your height, weight and "vital signs" (blood pressure and heart rate).
- You will receive instructions for the low- and high-salt dietary protocols.
- Give you instruction and train you on 24-hour blood pressure monitoring and provide you with a blood pressure monitor. This will be done before each of the subsequent study visits (three times).
- Give you instruction and train you on 24-hour urine collections and provide you with a container to collect your urine. You will be instructed to keep the urine collection jug cold through refrigeration or use of provided insulated cooler bag. This will be done before each of the subsequent study visits (three times).
- Randomize you to one of the following dietary sequences: (1) high-salt, then low-salt diet; or (2) low-salt, then high-salt diet.
- Give you instructions on maintaining your current lifestyle behaviors, for example, the same usual level of activity, during the remainder of the study period. We will also give you to instructions to maintain your "usual" diet between now and the next (baseline) study visit.

Baseline visit (Approximately Day 7):
Two days prior to this baseline visit, we will send you an email, text message (SMS message), and/or phone call (according to your preference) to remind you that on the following day (which is the day prior to baseline visit) you will need to start your 24-hour urine collection and 24 hour blood pressure monitor. SMS (short message service) is a text messaging service that uses short messages consisting of words and/or numbers. The day prior to your baseline visit, we will also send you an email, text message (SMS message), and/or phone call, reminding you to collect your urine and wear your blood pressure monitor. You will need to bring the urine collection and blood pressure monitor with you to the baseline visit.

For this baseline visit, you will arrive fasting (≥ 6 hours). This means that you cannot eat or drink anything (except medications) for at least 6 hours before this visit. Upon your arrival to the research facility, you will be asked to turn in your urine collection and blood pressure monitor. Your weight will be measured. You will be asked to lay flat on your back for 30 minutes. During this time, your blood pressure and heart rate will be recorded 3 times with 5 minutes between each recording. The study coordinator will download your 24-hour blood pressure monitor recordings. You will also receive repeated instruction on 24-hour urine collection and 24-hour blood measure monitor that you will again start the day prior to your next study visit. After 30 minutes and while you are still flat on your back, a healthcare professional (e.g. nurse, phlebotomist, or trained coordinator) will draw about 30 ml (about 2 tbsp.) of venous blood from your arm. Some of these blood samples will be stored for future investigations. Your urine will be stored for future investigations.

Following your blood draw and based on the pre-assigned randomization order, you will then be given either the 1-week of low-salt meals and sodium free water or high-salt bullion packets and calcium supplements. You will begin consuming the appropriate diet on that day.

This baseline visit should be about 1 hour in duration.

Diet 1 visit (Approximately Day 14):
Each day between your baseline visit and this Diet 1 visit, you will receive an email, text message (SMS message), and/or phone call (according to your preference) to remind you to adhere to the pre-assigned study diet.

Two days prior to this Diet 1 visit, we will send you an email, text message (SMS message), and/or phone call (according to your preference) to remind you that on the following day (which is the day prior to Diet 1 visit) you will need to start your 24-hour urine collection and 24-hour blood pressure. The day prior to your Diet 1 visit, we will also send you an email, text message (SMS message), and/or phone call, reminding you to collect your urine and wear your blood pressure monitor. You will need to bring the urine collection and blood pressure monitor with you to the Diet 1 visit.

Just as with the baseline visit, for this Diet 1 visit, you will arrive fasting (≥ 6 hours). This means that you cannot eat or drink anything (except medications) for at least 6 hours before this visit. Upon your arrival to the research facility, you will be asked to turn in your urine collection and blood pressure monitor. Your weight will be measured. You will be asked to lay flat on your back for 30 minutes. During this time, your blood pressure and heart rate will be recorded 3 times with 5 minutes between each recording. The study coordinator will download your 24-hour blood pressure monitor recordings. You will also receive repeated instruction on 24-hour urine collection and 24-hour blood measure monitor that you will again start the day prior to your next study visit. After 30 minutes and while you are still flat on your back, a healthcare professional (e.g. nurse, phlebotomist, or trained coordinator) will draw about 30 ml (about 2 tbsp.) of venous blood from your arm. Some of these blood samples will be stored for future investigations. Your urine will be stored for future investigations.

Following your blood draw and based on the pre-assigned randomization order, you will then be given the opposite diet to what you just consumed. This will either be the 1-week low-salt meals and sodium free water

or high-salt bullion packets and calcium supplements. You will begin consuming the appropriate diet on that day.

This Diet 1 visit should be about 1 hour in duration.

Diet 2 visit (Approximately Day 21):
Each day between your Diet 1 visit and this Diet 2 visit, you will receive an email, text message (SMS message), and/or phone call (according to your preference) to remind you to adhere to the pre-assigned study diet.

Two days prior to this Diet 2 visit, we will send you an email, text message (SMS message), and/or phone call (according to your preference) to remind you that on the following day (which is the day prior to Diet 2 visit) you will need to start your 24 hour urine collection and 24 hour blood pressure. The day prior to your Diet 2 visit, we will also send you an email, text message (SMS message), and/or phone call, reminding you to collect your urine and wear your blood pressure monitor. You will need to bring the urine collection and blood pressure monitor with you to the Diet 2 visit.

Just as with the baseline and Diet 1 visit, for this Diet 2 visit, you will arrive fasting (≥ 6 hours). This means that you cannot eat or drink anything (except medications) for at least 6 hours before this visit. Upon your arrival to the research facility, you will be asked to turn in your urine collection and blood pressure monitor. Your weight will be measured. You will be asked to lay flat on your back for 30 minutes. During this time, your blood pressure and heart rate will be recorded 3 times with 5 minutes between each recording. The study coordinator will download your 24-hour blood pressure monitor recordings. After 30 minutes and while you are still flat on your back, a healthcare professional (e.g. nurse, phlebotomist, or trained coordinator) will draw about 30 ml (about 2 tbsp.) of venous blood from your arm. Some of these blood samples will be stored for future investigations. Your urine will be stored for future investigations.

Following your blood draw, your study period will be complete. This Diet 2 visit should be about 1 hour in duration.

Low-salt and high-salt diets:
Each diet lasts for 7 days.

For your low-salt diet, we will prepare all your meals for you, to make sure that the salt in the food is low enough. We will provide the meals and bottled water to you at no cost. These meals will contain all the nutrients required for a healthy diet. While on the one week of low salt diet, you can only eat the food and drink the beverages that we prepare and provide for you during this time. You cannot eat or drink anything outside of this.

For your high-salt diet, you will not be restricted from following your normal diet. However, every day during this one week, your diet will be supplemented with 2 broth packets that can either be dissolved in water as soup or mixed into your food. We will provide you with the broth packets. Adding the broth to your usual diet is a way to make sure that there is enough salt in your diet to be considered “high salt.” You will need to eat all the food or drink all of the liquid into which you dissolve the broth packets. You will be able to drink as much water as you like during this time.

While on the high-salt diet, you will be asked to take calcium (e.g. 2 Tums ® tablets a day). These will be provided to you at no cost as part of this research study.

24-hour blood pressure monitoring:
This is a well-tolerated procedure available in standard clinical practice. The device is lightweight (9 oz), compact, and fits in a provided carrying pouch, shirt or pant pocket to optimize ease of use. Blood pressure recordings will be made automatically by the device using the same protocol utilized in the CARDIA year 5 exam to allow potential comparisons. Blood pressure will be measured every 20 minutes between 6:00 am and

10:00 pm and every 30 minutes from 10:00 pm to 6:00 am. Values outside of preset ranges, ≥220 or ≤80 mm Hg systolic and ≥130 or ≤40 mm Hg diastolic, will prompt repeat measures. A change of 50 mm Hg systolic, 40 mm Hg diastolic, or 50 mm Hg in pulse pressure between readings will also trigger a new measurement.

The 24-hour blood pressure recordings will be reviewed at the Vanderbilt Translational and Clinical Cardiovascular Research Center reading lab within 72 hours and any safety reports will be generated as appropriate. Sustained, for three consecutive readings, BP > 180/120 or < 90/50 will generate a safety report and will be relayed to the respective Field Center and by them to the participant, with referral for follow-up care.

Incidental Findings and Clinical Results

From the baseline visit exam, we will provide you with the results of your in-clinic blood pressure readings. In addition, we will send you a report of your baseline 24-hour ambulatory blood pressure monitor. After completing the low- and high-salt diets, we will also send you a report regarding how much your blood pressure changed between these two diets. The urine and blood samples will not be analyzed until a later date (approximately 2022-2023) and therefore the results of these tests will not be provided to you. The results from the data and specimens we collect in this study are not reviewed by a study physician in the same manner as what you would receive as part of your routine health care with your own doctors. The results of your data will not be placed in your medical record with your primary care physician or otherwise. You may choose, however, to share the reports we provide you with your own doctors. If while you are on the study diets (low- or high-salt) you are having symptoms that may require care, you should contact the designated study coordinator or physician, or your own physician.

Additional Information

Your de-identified private information and de-identified biospecimens (private information and biospecimens with all identifiers removed) may be used for future research studies or distributed to another researcher for future research studies without additional informed consent.

Risks and Discomforts

You may experience one or more of the risks indicated below from being in this study. In addition to these, there may be other unknown risks, or risks that we did not anticipate, associated with being in this study.

Blood draw. You may have a small amount of bleeding, pain, infection or allergic reaction at the needle stick site. These risks are minimal and usually resolve without any specific medical therapy over the course of minutes to days.

Fasting, low- and high-salt diets. Occasionally, fasting, as well as low- and high-salt diets can cause low and high blood volume responses, respectively. You will be informed of symptoms of low or high blood volume and you will be monitored when you report to your study visits.

There are no known risks to 24-hour ambulatory blood pressure monitoring.

Benefits

You will not benefit from taking part in this study. The results of this research study may advance our understanding of the biologic mechanisms for salt-sensitivity of blood pressure and inform novel preventative and therapeutic strategies. This could benefit patients in the future.

Alternatives

This is not a treatment study. You do not have to be in this research study.

Confidentiality and Authorization to Use and Disclose Information for Research Purposes

Federal regulations give you certain rights related to your health information. These include the right to know who will be able to get the information and why they may be able to get it. The study doctor must get your authorization (permission) to use or give out any health information that might identify you.

What protected health information may be used and/or given to others? All medical information, including but not limited to information and/or records of any diagnosis or treatment of disease or condition, which may include sexually transmitted diseases (e.g., HIV, etc.) or communicable diseases, drug/alcohol dependency, etc.; all personal identifiers, including but not limited to your name, social security number, medical record number, date of birth, dates of service, etc.; any past, present, and future history, examinations, laboratory results, imaging studies and reports and treatments of any kind, including but not limited to drug/alcohol treatment, psychiatric/psychological treatment; financial/billing information, including but not limited to copies of your medical bills; any other information related to or collected for use in the research study, regardless of whether the information was collected for research or non-research (e.g., treatment) purposes; records about any study drug you received or about study devices used; and consent forms from past studies that might be in your medical record.

A description of this clinical trial will be available on www.clinicaltrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this Web site at any time.

Who may use and give out this information? Information about your health may be used and given to others by the study doctor and staff. They might see the research information during and after the study.

Who might get this information? All individuals/entities listed in the informed consent document(s), including but not limited to, the physicians, nurses and staff and others performing services related to the research (whether at UAB or elsewhere). Your information may also be given to the sponsor of this research. "Sponsor" includes any persons or companies that are working for or with the sponsor, or are owned by the sponsor, or are providing support to the sponsor (e.g., contract research organization).
Information about you and your health which might identify you may be given to:

- the Office for Human Research Protections (OHRP)
- the U.S. Food and Drug Administration (FDA)
- Department of Health and Human Services (DHHS) agencies
- Governmental agencies in other countries
- Governmental agencies to whom certain diseases (reportable diseases) must be reported
- the University of Alabama at Birmingham - the physicians, nurses and staff working on the research study (whether at UAB or elsewhere); other operating units of UAB, UAB Hospital, UAB Highlands Hospital, as necessary for their operations; the UAB IRB and its staff
- the billing offices of UAB and UAB Health Systems affiliates

As part of the study, Dr. Lewis and their study team may share the results of your study and/or non-study linked information that may be reasonably related to the conduct and oversight of this research study, as well as parts of your medical record, to the groups named below. These groups may include people from, Northwestern University, and/or Vanderbilt University Institutional Review Boards, staff within Northwestern University, and Vanderbilt University Medical Center who need the information to do their jobs (such as billing, or for overseeing the quality and care for research), people we hire to do work for us (such as data storage companies, our insurers, or our lawyers), federal and state agencies (such as , the National Institutes of Health), the CARDIA Observational Study Monitoring Board, organizations that make sure hospital standards are met, other researchers and medical centers that are part of this research study, and a group that oversees the data

(study information) and safety of this research study. 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.

Why will this information be used and/or given to others? Information about you and your health that might identify you may be given to others to carry out the research study. The sponsor will analyze and evaluate the results of the study. In addition, people from the sponsor and its consultants will be visiting the research site. They will follow how the study is done, and they will be reviewing your information for this purpose.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the National Institutes of Health, National Heart, Lung and Blood Institute, and Vanderbilt University which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law in regards to suspicion of participant abuse or neglect or possible harm by participant to self or others.

The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document.

Other scientists may request data obtained by the CARDIA Study. We will allow data to be released to others only after ensuring that all your identifiable information is removed. Any information we obtain will only be used for scientific and research purposes. In any report or article about this study or if we share the study data set with others, we will describe the study results in a summarized manner so that you cannot be identified.

What if I decide not to give permission to use and give out my health information? By signing this consent form, you are giving permission to use and give out the health information listed above for the purposes described above. If you refuse to give permission, you will not be able to be in this research study.

May I review or copy the information obtained from me or created about me? You have the right to review and copy your health information. However, if you decide to be in this study and sign this permission form, you will not be allowed to look at or copy your information until after the research is completed.

May I withdraw or revoke (cancel) my permission? Yes, but this permission will not stop automatically. The use of your personal health information will continue until you cancel your permission.

You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the study site-principal investigator. If you withdraw your permission, you will not be able to continue being in this study.

When you withdraw your permission, no new health information which might identify you will be gathered after that date. Information that has already been gathered may still be used and given to others. This would be done if it were necessary for the research to be reliable.

Is my health information protected after it has been given to others? If you give permission to give your identifiable health information to a person or business, the information may no longer be protected. There is a risk that your information will be released to others. Including others outside of UAB, without your permission.

Your study records and data will be stored in a secure database. The database will reside in a password protected secure website supported by Vanderbilt University Medical Center, known as REDCap. Only key study personnel will have access to the database. Information in the database that will identify you will only be available to study personnel at your local field center.

This study will follow the relevant federal guidelines regarding HIPAA regulations on patient-related information. As stated above, only key study personnel at your local field center will have access to identified information.

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.

The study results will be kept in your research record for at least six years after the study is finished. After that time, the research data will be kept for an unknown length of time. Any research data that has been put into your CARDIA record will be kept for an unknown length of time.

Voluntary Participation and Withdrawal

Whether or not you take part in this CARDIA Salt-sensitivity of Blood Pressure Ancillary Study is your choice. There will be no penalty if you decide not to be in it. If you decide not to be in the study, you will not lose any benefits you are otherwise owed. You are free to withdraw from this research study at any time. Your choice to leave the study will not affect your relationship with this institution. Regardless of your choice, you have the right to be treated with respect, including respect for your decision whether or not you wish to continue or stop being in the study. If after you complete the testing, you would like to withdraw from this ancillary study and not have your test results used in the research, you may do so in writing by contacting:

Cora E. Lewis, MD, MSPH
1717 11th Avenue South | MT 700 | Birmingham, AL 35205

At that time, the health data we have stored before you withdrew your consent may still be used for reporting and research quality.

Under certain circumstances, the researchers might decide to end your participation in this research study earlier than planned. This might happen if study investigators determine that it would not be safe for you to continue participating. Your doctor may remove you from the study if you experience complications during any of the discussed procedures. For female subjects, you will be removed from the study should you become pregnant during the timeframe of your participation. Your participation in this study may also be terminated if you are no longer able to provide your consent to continue.

If you are a student or employee at this institution, taking part in this research is not a part of your class work or duties. You can refuse to enroll, or withdraw after enrolling at any time before the study is over, with no effect on your class standing, grades, or job at this institution. You will not be offered or receive any special consideration if you take part in this research.

Costs of participation

There will be no cost to you for taking part in this study. All medical tests, meals, broth packets and calcium supplements (e.g., Tums) related to this study will be provided to you at no cost during this 1-month period. If you choose text messages for your preferred method of contact, you may incur standard data rates.

Payments for participation in the research

You will be paid $275 in total for completing the entire study, which will be paid as $25 for completion of the baseline SSBP visit, $25 for completion of Diet-1 visit, and the remaining $225 after completion of all three study SSBP visits. This amount may be taxable and will be reported to the Internal Revenue Service (IRS). We will ask you for your Social Security number and address before you are compensated for taking part in this study. Ask the study staff about the methods of payment that will be used for this study (e.g., check, cash, gift card, direct deposit).

New Findings

You will be told by Dr. Lewis or her study staff if new information becomes available that might affect your choice to stay in this study.

Optional/Storage of samples for future research

Your blood and urine samples will be shipped to Vanderbilt University Medical Center Core Lab for Cardiovascular Translational and Clinical Research and will not be analyzed until a later date (approximately 2022-2023). Remaining blood and urine samples will be stored for future investigations.

The future research may be similar to this study or may be completely different. Your private information and biospecimens will be stored indefinitely or until used.

You can take part in this study even if you decide not to let us keep your coded private information and coded biospecimens for future research.

If you give us permission now to keep your coded private information and coded biospecimens, you can change your mind later and ask us to destroy it. However, once we have analyzed your private information and biospecimens, we may not be able to take it out of our future research.

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 your samples. These tests may help us learn more about the causes, risks, treatments, or how to prevent this 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 Medical Center, and/or others. If this happens, there are no plans to provide money to you.

To help protect your confidentiality, we will use a unique CARDIA ID to identify you. Specimens shipped outside of a Field Center are coded with a unique CARDIA ID; in this ancillary study we will use the CARDIA ID and a unique coded specimen ID, neither of which contain any protected health information. All specimens will be shipped to Vanderbilt University Medical Center.

Please initial your choice below.

_____Yes, I agree to storage of my coded biospecimens, at Vanderbilt University Medical Center, for future research.

_____No, I do not agree to storage of my coded bio specimens, at Vanderbilt University Medical Center, for future research.

Questions

If you have any questions about any aspect of this study, a staff person will be on hand to answer them before you sign this consent form. If you have any questions at any time regarding this study, please contact Dr. Cora E. Lewis at (205) 934-2294. You may also call Ms. Kelly Hardy, CARDIA Clinic Coordinator at (205) 934-2024 or a member of the CARDIA Clinic Staff at (205) 934-6330.

If you have questions about your rights as a research participant, or concerns or complaints about the research, you may contact the UAB Office of the IRB (OIRB) at (205) 934-3789 or 1-855-860-3789. Regular hours for the OIRB are 8:00 a.m. to 5:00 p.m. CT, Monday through Friday.

Legal Rights

You are not waiving any of your legal rights by signing this consent form.

Signatures

Your signature below indicates that you have read (or been read) the information in this consent form and you agree to participate in this study. You will receive a copy of this signed consent form to keep.

_____	_____
Signature of Participant	Date
_____	_____
Signature of Person Obtaining Consent	Date