Informed Consent Cover Page for FDAAA consent posting:

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STUDY TITLE: Genomics, Environmental Factors and Social Determinants of Cardiovascular Disease in African-Americans Study (GENE-FORECAST): Sodium Intervention Trial (SIT)/**GENE-FORECAST SIT**

STUDY SITE: National Institutes of Health, NIH, Clincial Center, (CC)

Cohort: Healthy Volunteer

Consent Version: 12/21/2020

WHO DO YOU CONTACT ABOUT THIS STUDY?

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KEY INFORMATION ABOUT THIS RESEARCH

This consent form describes a research study and is designed to help you decide if you would like to be a part of the research study.

You are being asked to take part in a research study at the National Institutes of Health (NIH). This section provides the information we believe is most helpful and important to you in making your decision about participating in this study. Additional information that may help you decide can be found in other sections of the document. Taking part in research at the NIH is your choice.

Taking part in NIH research is entirely voluntary.

This study may show us how your body responds to increased levels of sodium (salt).

If you decide to participate, you will be enrolled for 7 weeks, as an outpatient.

You will take a salt capsule or placebo capsule .(no salt.)

You will be instructed to take;

- 3 pills per day for a total of 3 grams (3000mg) of sodium for a two week period
- followed by a 3 week wash-out period (length of time you will not take any pills)
- final two week period of the salt/placebo capsule, 3 pills per day for a total of 3 grams.

You will complete four visits to the Clinical Center where you will:

- complete a physical examination,
- complete skin swab and salvia collection,
- complete questionnaires,
- have blood drawn, complete a vascular function test and

- participate in a taste test.

Sodium chloride (salt) is approved by the Food and Drug and Administration (FDA) and availaable over-the-counter (OTC).

The amount of salt you will be taking on a daily basis is equal to about half a teaspoon of salt or a packet of Ramen chicken noodle soup.

The salt capsules are well tolerated but side effects can occur including discomfort while swallowing, increased thirst, indigestion, nausea, vomiting headaches, mild elevations in blood pressure, mild changes in blood chemicals (electrolytes), lightheadedness, tiredness, mild swelling of arms/legs, and/or diarrhea.Although it would be very rare to have an allergic reaction to the capsules in this study, any time a new medication is taken there is a small chance (less than 1 person out of 1000 treated) that an allergic reaction could occur which would most commonly manifest itself as a rash. You will not be able to take antibiotics for the duration of the study. Please notify study staff if you become pregnant or miss a dose for instructions. You will be excluded from the study if you are no longer able to consent for study participation.

You may choose not to take part, or you may withdraw from the study at any time. In either case, you will not lose any benefits to which you are otherwise entitled. However, to receive care at the NIH, you must be taking part in a study or be under evaluation for study participation.

You may receive no benefit from taking part. The research may give us knowledge that may help people in the future.

Why were you selected?

The **GENE-FORECAST- Sodium Intervention Trial** (GENE-FORECAST SIT) is a follow- up study to the **GENE- FORECAST** study in which you participated. You are being asked to participate in **GENE- FORECAST- SIT** because you are an African-American man or woman born in the United States, and are between the ages of 21 and 65. You have also been selected because you are not pregnant or breast feeding) nor have you had a heart attack, stroke, or heart failure within the past 12 months.

Furthermore, you are being selected because you are not currently taking any prescribed medications and have not been diagnosed with high blood pressure, depression, kidney disease, liver disease and/or diabetes.

The remaining document will now describe the research study in more detail. This information should be considered before you make your choice. Members of the study team will talk with you about the information in this document. Some people have personal, religious, or ethical beliefs that may limit the kinds of medical or research treatments they would want to receive (such as blood transfusions). Take the time you need to ask any questions and discuss this study with NIH staff, and with your family, friends, and personal health care providers.

IT IS YOUR CHOICE TO TAKE PART IN THE STUDY

You may choose not to take part in this study for any reason. If you join this study, you may change your mind and stop participating in the study at any time and for any reason. In either case, you

will not lose any benefits to which you are otherwise entitled. However, to be seen at the NIH, you must be taking part in a study or are being considered for a study. If you do choose to leave the study, please inform your study team to ensure a safe withdrawal from the research.

WHY IS THIS STUDY BEING DONE?

This is a research study. The purpose of this **GENE-FORECAST- SIT** research study is to better understand your body's response to adding more salt to your diet. We are particularly interested in assessing any effect on your blood pressure, the health of your arteries and the genes expressed in your blood. You will be in the study for 7 weeks.

This study compares your body's response to two dietary treatments and consists of a total of four visits to the NIH. During the first visit, you will have tests performed and receive capsules containing either salt or placebo based on random selection (the dietary treatment you receive first will be determined by a process similar to flipping a coin). You will not know which treatment you are getting because the capsules containing either salt or placebo look and taste the same. You will be instructed to take three capsules per day, two in the morning and one in the evening for two weeks. At the end of this two- week treatment period, you will return for a second visit to the NIH for additional tests to assess how your body responds to taking the capsules. After you complete the first treatment, you will enter a 'washout' period during which you do not take any capsule treatments. After the three- week 'washout' period, you will come back to the NIH for your third visit for another set of baseline tests and begin the second two-week capsule treatment period. After the two-week capsule treatment period, you will return to the NIH for your fourth and final visit for tests that assess how your body responds to the second round of capsule treatment. We are asking you to join this research study because you are an African-American man or woman born in the United States, and are between the ages of 21 and 65. You have also been selected because you are not pregnant (or breast feeding) nor have you had a heart attack, stroke, or heart failure within the past 12 months.

Furthermore, you are being selected because you are not currently taking any prescribed medications and have not been diagnosed with high blood pressure, depression, kidney disease, liver disease and/or diabetes.

DYWHAT WILL HAPPEN DURING THE STUDY?

If you decide to take part in this study, you will be asked to come to the National Institutes of Health (NIH) Clinical Center in the morning for evaluation in a fasting state (before eating breakfast) for each of the visits outlined above. Visits usually take about 4.5 hours, but will take no longer than 5.5 hours in the NIH Clinical Center for all of your tests during each visit.

Screening Activities

Participant who agree to participate in the study will be scheduled for a baseline clinical visit based on availability and subsequently screened again at the Clinical Center. All participants will undergo screening activities upon coming to the NIH. Female participants will undergo a pregnancy test after consent signature. Participants who consent to participate in the trial and subsequently have a positive pregnancy test prior to randomization will be considered a screen

failure and not enrolled in the study. In addition, participants who consent to participate but present with systolic blood pressure (SBP) >140 mm Hg and diastolic blood pressure (DBP) >90 mm Hg at physical examination will also be considered a screen failure and not enrolled.

The table below illustrates the tests which will be performed during each of your visits. At any given time, neither you nor the protocol staff will know whether you are taking salt capsules or placebo capsules. It is important that you continue your usual dietary habits throughout the duration of the study.

Test performed	Visit 1 (baseline)	Visit 2 (after 2-week treatment)	Visit 3 (after 3-week washout)	Visit 4 (after second 2-week treatment)
24hr recall food intake	X	X	X	X
Psychophysical Taste Task: Sucrose and Salt Detection Thresholds	X	X	X	X
Psychophysical Taste Task: Sucrose and Salt Preference	X	X	X	X
History& physical exam with medication history	X	X	X	X
Physical activity questionnaire	X			
Sleep questionnaire	X			
Stool/skin/mouth specimen collection	X	X	X	X
Urine sample	X	X	X	X
Blood sample	X	X	X	X

Vascular function	X	X	X	X
24-hour blood pressure monitor given to participant		X		X

24 Hour food intake recall: You will be asked a series of questions by staff from the Clinical Center Nutrition Department to recall any foods or beverages you may have eaten or drank over the past 24 hours.

A Psychophysical Taste Task with sucrose and salt detection thresholds: Sucrose and salt detection thresholds will be assessed to get your responses to sweetness or saltiness. You will do this at each of your visits to the NIH.

A Psychophysical Taste Task using sucrose and salt preference: Sucrose and salt preference will be assessed to get your responses to sucrose and salt. You will do this at each of your visits to the NIH.

Physical Activity and Sleep Questionnaire: You will be asked a series of questions related to your physical activity and sleep. These questionnaires will be administered by GENE-FORECAST-SIT staff during your visit.

Physical Exam: During each visit a medical history (including any medication changes) will be obtained by a GENE- FORECAST-SIT staff member and a physical exam will be performed.

Microbiome Collection: One of the goals of this study is to measure how changes in the amount of salt in your diet may affect your bacteria. We now know that in normal, healthy individuals, there are bacteria and other tiny organisms that co-exist in our digestive tract or gut. These bacteria co-exist in your body in a mutually beneficial way and contribute to your well-being by helping you digest the food you eat. During this study, we will measure the different types of bacteria living in your digestive tract by running tests on the stool specimens you provide during the study. In addition, we will also measure the bacteria that normally live in your mouth saliva and skin. Providing study samples of these specimens that the body normally excretes will not cause you any additional pain or discomfort. You should not take a shower for 12 hours prior to sample collection.

Stool: You will be provided with a stool specimen collection kit via postal services prior to your visit. You will collect your stool specimen at your residence, within 48 hours of your visit, and bring your stool specimen to your NIH Clinical Center visit to measure the different types of bacteria living in your digestive tract by running tests on the stool specimens. You will do this for each of your visits to the NIH.

Skin: At each clinical center visit, GENE-FORECAST-SIT staff will use sterile collection swabs to collect samples of skin from behind the ears and the inner part of the elbow to measure the bacteria that normally live on your skin.

Mouth: At each clinical center visit, saliva samples from your mouth will be collected by passive drool or spit using a sterile collection tube to measure the bacteria that normally live in your mouth saliva.

Urine: You will be asked to give a urine sample in a cup provided to you at the NIH Clinical Center to test for urine chemistries (e.g., potassium, chloride, sodium). Genetic information from urine will be used to investigate genes that affect cardiovascular diseases and how those genes are influenced by physical and social environments and behavior.

Blood collection: You will have blood drawn for your fasting blood lab tests. About 5 to 6 tablespoons will be drawn by standard procedures. Part of your blood sample will be used for special biological specimens. Genetic information from blood will be used to investigate genes that affect cardiovascular diseases and how those genes are influenced by physical and social environments and behavior.

HOW LONG WILL THE STUDY TAKE?

If you agree to take part in this study, your involvement is expected to last for 7 weeks, for a total of 4 study visits. Visits usually take about 4.5 hours, but will take no longer than 5.5 hours in the NIH Clinical Center for all of your tests during each visit.

HOW MANY PEOPLE WILL PARTICIPATE IN THIS STUDY?

We plan to have approximately 40 people participate in this study at the NIH.

WHAT ARE THE RISKS AND DISCOMFORTS OF BEING IN THE STUDY?

There are different kinds of risk that you may face if you join the study. The risks are very minor and include:

Vascular function testing and 24-hour blood pressure monitor: You may experience brief physical discomfort, pain or tingling sensations when the blood pressure cuff is inflated to reduce blood flow to the hand for a few minutes during the vascular function tests and/or 24-hour blood pressure monitor.

Blood Draw: Mild discomfort, redness, and minor physical bruising may occur when your blood is drawn. Infections at the needle site may occur. On rare occasions you may feel faint.

Microbiome collection: Collection will comprise skin, saliva and stool samples utilizaing Norgen kits. These tests carry very minor risks, with the transient mild skin irritation at the sites where your skin is swabbed although this is very unlikely.

Salt capsules: Sodium chloride is approved by the Food and Drug Administration (FDA) for a variety of clinical uses. The capsules which you will be given as part of this study contain sodium chloride (salt) in powder form or placebo. The amount of salt you will be adding to your usual daily diet as part of this study is equivalent to about half a teaspoon of salt or a packet of Ramen chicken noodle soup. The salt capsules are generally safe and well tolerated but side effects can occur including discomfort while swallowing, increased thirst, indigestion, nausea, vomiting, headaches, mild elevations in blood pressure, mild changes in blood chemicals (electrolytes), lightheadedness, tiredness, mild swelling of arms/legs, and/or diarrhea. Although it would be very rare to have an allergic reaction to the capsules in this study, any time you take a new medication there is a small chance (less than 1 person out of 1000 treated) that you could have an allergic reaction which would most commonly manifest itself as a rash. The GENE-FORECAST-SIT staff will monitor you closely during study participation to detect any potential serious adverse reactions to the salt capsules.

24 Hour food intake recall: You will be asked a series of questions by staff from the Clinical Center Nutrition Department to recall any foods or beverages you may have eaten or drank over the past 24 hours. There may be a minor psychological risk of not being able to recall any food or beverage item questions over the past 24 hours.

Mouth: At each clinical center visit, saliva samples from your mouth will be collected by passive drool or spit using a sterile collection tube. Providing study samples of these specimens that the body normally excretes will not cause you any additional pain or discomfort.

Stool: You will be provided with a stool specimen collection kit prior to your visit. There may be physical discomfort of inability to obtain sample (e.g , constipation). Providing study samples of these specimens that the body normally excretes will not cause you any additional pain or discomfort.

Urine: You will be asked to give a urine sample in a sterile cup provided to you at the NIH Clinical Center to test for urine chemistries (e.g., potassium, chloride, sodium). There may be physical limitations in inability to provide sample (e.g. dehydration).Providing study samples of these specimens that the body normally excretes will not cause you any additional pain or discomfort.

Psychophysical Taste Task with sucrose and salt detection thresholds and preference**:** Sucrose and salt detection thresholds and preference will be assessed to get your responses to sweetness or saltiness. There may be a physical discomfort of tasting solutions and repeated spitting action to discard solution in a waste receptacle.

Physical activity and sleep questionnaire: You will be asked a series of questions related to your physical activity and sleep. You may experience minor emotional discomfort in answering personal questions regarding your physical activity and sleeping habits.

The GENE-FORECAST-SIT staff will make an attempt to contact you between 1 to 2 times a week during the treatment phase of the trial to ask you how you are responding. The mobile telephone numbers of the GENE- FORECAST-SIT staff will also be provided to you so you may call if you have any issues to discuss while at home.

WHAT ARE THE BENEFITS OF BEING IN THE STUDY?

You will not benefit from being in this study.

Are there any potential benefits to others that might result from the study?

In the future, other people might benefit from this study by improving our knowledge of the relationship between salt and health in African-Americans.

WHAT OTHER OPTIONS ARE THERE FOR YOU?

Before you decide whether or not to be in this study, we will discuss other options that are available to you. Instead of being in this study, you could receive a thorough check-up for cardiovascular disease from your doctor.

DISCUSSION OF FINDINGS

New information about the study

If we find out any new information that may affect your choice to participate in this study, we will get in touch with you to explain what we have learned. This may be information we have learned while doing this study here at the NIH or information we have learned from other scientists doing similar research in other places.

Return of research results

You will be mailed a letter following your baseline visit at the NIH Clinical Center with results from your clinical visit, including Body Mass Index with health definitions, glucose, and blood pressure. Genetic counseling will not be provided. We are not performing gene sequencing as a part of the study, therefore reporting the possibility of incidental findings is not applicable.

EARLY WITHDRAWAL FROM THE STUDY

You are free to withdraw from participation in the study at any time upon request. If you do wish to end your participation in the study, we need to talk with you about how to do this. We need to

know if you want to stop future interactions with us, whether we can keep using your samples, etc. We will make reasonable efforts to comply with your wishes.

STORAGE, SHARING AND FUTURE RESEARCH USING YOUR SPECIMENS AND DATA

As part of this study, we are obtaining specimens and data from you. We will remove all the identifiers, such as your name, date of birth, address, or medical record number and label your specimens and data with a code so that you cannot easily be identified. However, the code will be linked through a key to information that can identify you. We plan to store and use these specimens and data for studies other than the ones described in this consent form that are going on right now, as well as studies that may be conducted in the future. These studies may provide additional information that will be helpful in understanding Cardiovascular Disease, or other diseases or conditions. This could include studies to develop other research tests, treatments, drugs, or devices, that may lead to the development of a commercial product by the NIH and/or its research or commercial partners. There are no plans to provide financial compensation to you if this happens. Also, it is unlikely that we will learn anything from these studies that may directly benefit you.

I give permission for my coded specimens and data to be stored and used for future research as described above.

_____ Yes _____ No

Initials Initials

Will your specimens or data be shared for use in other research studies?

We may share your coded specimens and data with other researchers. If we do, while we will maintain the code key, we will not share it, so the other researchers will not be able to identify you. They may be doing research in areas that are similar to this study or in other unrelated areas. These researchers may be at NIH, other research centers and institutions, or commercial entities.

I give permission for my coded specimens and data to be shared with other researchers and used by these researchers for future research as described above.

_____ Yes _____ No

Initials Initials

If you change your mind and do not want us to store and use your specimens and data for future research, you should contact the research team member identified at the top of this document. We will do our best to comply with your request but cannot guarantee that we will always be able to destroy your specimens and data. For example, if some research with your specimens and data has already been completed, the information from that research may still be used. Also, for example, if the specimens and data have been shared already with other researchers, it might not be possible to withdraw them.

In addition to the planned use and sharing described above, we might remove all identifiers and codes from your specimens and data and use or share them with other researchers for future research at the NIH or other places. When we or the other researchers access your anonymized data, there will be no way to link the specimens or data back to you. We will not contact you to ask your permission or otherwise inform you before we do this. We might do this even if you answered "no" to the above questions. If we do this, we would not be able to remove your specimens or data to prevent their use in future research studies, even if you asked, because we will not be able to tell which are your specimens or data.

NIH policies require that your clinical and other study data be placed in an internal NIH database that is accessible to other NIH researchers for future research.

Usually, these researchers will not have access to any of your identifiers, such as your name, date of birth, address, or medical record number; and your data will be labeled with only a code. We cannot offer you a choice of whether your data to be placed in this database or not. If you do not wish to have your data placed in this database, you should not enroll in this study.

NIH policies require that genomic data be placed in a repository for sharing. Therefore, we cannot offer you a choice of whether your data will be shared. If you do not wish to have your data placed in a repository, you should not enroll in this study.

How long will your specimens and data be stored by the NIH?

Your specimens and data may be stored by the NIH, possibly indefinitely.

Risks of storage and sharing of specimens and data

When we store your specimens and data, we take precautions to protect your information from others that should not have access to it. When we share your specimens and data, we will do everything we can to protect your identity, for example, when appropriate, we remove information that can identify you. Even with the safeguards we put in place, we cannot guarantee that your identity will never become known or someone may gain unauthorized access to your information.

New methods may be created in the future that could make it possible to re-identify your specimens and data.

COMPENSATION, REIMBURSEMENT, AND PAYMENT

Will you receive compensation for participation in the study?

Some NIH Clinical Center studies offer compensation for participation in research. The amount of compensation, if any, is guided by NIH policies and guidelines.

You will receive payment to compensate you for the time you spend in research study visits. The compensation amount for participation at the NIH Clinical Center will depend on the number of clinical visits and completion of the study, including collection of stool specimens, ambulatory blood pressure monitoring, taking capsules, and return of the ambulatory blood pressure device. Below describes the amount you will receive for each Clinical Center visit.

Description of visit	Compensation
Visit 1	$50
Visit 2	$50
Visit 3	$50
Visit 4	$50
Study Completion and return of blood pressure device	**$300**
Possible Total Compensation	**$500**

If you are unable to finish the study, you will receive compensation for the parts you completed.

With few exceptions, study compensation is considered taxable income that is reportable to the Internal Revenue Service (IRS). A "Form 1099-Other Income" will be sent to you if your total payments for research participation are $600 or more in a calendar year. If you have unpaid debt to the federal government, please be aware that some or all of your compensation may be automatically reduced to repay that debt on your behalf.

Will you receive reimbursement or direct payment by NIH as part of your participation?

Some NIH Clinical Center studies offer reimbursement or payment for travel, lodging or meals while participating in the research. The amount, if any, is guided by NIH policies and guidelines.

This study does not offer reimbursement for, or payment of, lodging.

Participant will receive a $25 meal voucher for lunch and each visit and be afforded a one-way pre-paid taxi trip to the NIH Clinical Center.

Will taking part in this research study cost you anything?

NIH does not bill health insurance companies or participants for any research or related clinical care that you receive at the NIH Clinical Center.

There are no outpatient out of pocket costs for participation for this study.

CLINICAL TRIAL REGISTRATION AND RESULTS REPORTING

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.

CONFIDENTIALITY PROTECTIONS PROVIDED IN THIS STUDY

Will your medical information be kept private?

We will do our best to make sure that the personal information in your medical record will be kept private. However, we cannot guarantee total privacy. Organizations that may look at and/or copy your medical records for research, quality assurance, and data analysis include:

- The NIH and other government agencies, like the Food and Drug Administration (FDA), which are involved in keeping research safe for people.
- National Institutes of Health Intramural Institutional Review Board

The researchers conducting this study and the NIH follow applicable laws and policies to keep your identifying information private to the extent possible. However, there is always a chance that, despite our best efforts, your identity and/or information about your participation in this research may be inadvertently released or improperly accessed by unauthorized persons.

In most cases, the NIH will not release any identifiable information collected about you without your written permission. However, your information may be shared as described in the section of this document on sharing of specimens and data, and as further outlined in the following sections.

Further, the information collected for this study is protected by NIH under a Certificate of Confidentiality and the Privacy Act.

The research study team plans to collect social security numbers from research participants for purposes of compensation. Participants can withhold their social security numbers and still participate in the research study, however you may not be able to receive compensation if you do so.

Certificate of Confidentiality

To help us protect your privacy, the NIH Intramural Program has received a Certificate of Confidentiality (Certificate). With this certificate, researchers may not release or use data or information about you except in certain circumstances.

NIH researchers must not share information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if requested by a court.

The Certificate does not protect your information when it:

1. is disclosed to people connected with the research, for example, information may be used for auditing or program evaluation internally by the NIH; or
2. is required to be disclosed by Federal, State, or local laws, for example, when information must be disclosed to meet the legal requirements of the federal Food and Drug Administration (FDA);
3. is for other research;
4. is disclosed with your consent.

The Certificate does not prevent you from voluntarily releasing information about yourself or your involvement in this research.

The Certificate will not be used to prevent disclosure to state or local authorities of harm to self or others including, for example, child abuse and neglect, and by signing below you consent to those disclosures. Other permissions for release may be made by signing NIH forms, such as the Notice and Acknowledgement of Information Practices consent.

Privacy Act

The Federal Privacy Act generally protects the confidentiality of your NIH medical information that we collect under the authority of the Public Health Service Act. In some cases, the Privacy Act protections differ from the Certificate of Confidentiality. For example, sometimes the Privacy Act allows release of information from your record without your permission, for example, if it is requested by Congress. Information may also be released for certain research purposes with due consideration and protection, to those engaged by the agency for research purposes, to certain federal and state agencies, for HIV partner notification, for infectious disease or abuse or neglect reporting, to tumor registries, for quality assessment and medical audits, or when the NIH is involved in a lawsuit. However, NIH will only release information from your medical record if it is permitted by both the Certificate of Confidentiality and the Privacy Act.

POLICY REGARDING RESEARCH-RELATED INJURIES

The NIH Clinical Center will provide short-term medical care for any injury resulting from your participation in research here. In general, no long-term medical care or financial compensation for research-related injuries will be provided by the NIH, the NIH Clinical Center, or the Federal Government. However, you have the right to pursue legal remedy if you believe that your injury justifies such action.

PROBLEMS OR QUESTIONS

If you have any problems or questions about this study, or about your rights as a research participant, or about any research-related injury, contact the Principal Investigator, Gary H. Gibbons M.D., gary.gibbons@nih.gov, Telephone 301-496-5166. *Other researchers you may call are:* CDR Nicole Plass-Hermitt, BSN, MPA., GENE-FORECAST@nih.gov, Telephone 301-451-3511. You may also call the NIH Clinical Center Patient Representative at 301-496-2626, or the NIH Office of IRB Operations at 301-402-3713, if you have a research-related complaint or concern.

CONSENT DOCUMENT

Please keep a copy of this document in case you want to read it again.

Adult Research Participant: I have read the explanation about this study and have been given the opportunity to discuss it and to ask questions. I consent to participate in this study.

Signature of Research Participant	Print Name of Research Participant	Date

Investigator:

Signature of Investigator	Print Name of Investigator	Date