UNIVERSITY OF MICHIGAN

CONSENT TO BE PART OF A RESEARCH STUDY

1. KEY INFORMATION ABOUT THE RESEARCHERS AND THIS STUDY

Study title:

Sodium effect on ALdosTerone and urinarY RNA (SALTY)

Company or agency sponsoring the study:

National Institutes of Health and University of Michigan

Names, degrees, and affiliation of the principal investigator:

J. Brian Byrd, MD, MS, University of Michigan Internal Medicine - Cardiology

1.1 Key Study Information

You may be eligible to take part in a research study. This form contains important information that will help you decide whether to join the study. Take the time to carefully review this information. You should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others such as your family, friends, or other doctors about joining this study. If you decide to join the study, you will be asked to sign this form before you can start study-related activities. Before you do, be sure you understand what the research study is about.

A research study is different from the regular medical care you receive from your doctor. Research studies hope to make discoveries and learn new information about diseases and how to treat them. You should consider the reasons why you might want to join a research study or why it is not the best decision for you at this time.

Research studies have different kinds of risks and risk levels, depending on the type of the study. You may also need to think about other requirements for being in the study. For example, some studies require you to travel to scheduled visits at the study site in Ann Arbor or elsewhere. This may require you to arrange travel, change work schedules, find childcare, or make other plans. In your decision to participate in this study, consider all these matters carefully.

This research is studying whether a high or low salt diet has an impact on the way your genes handle salt. By studying your blood and urine while eating these high and low salt meals, the study team may find information that may simplify the diagnosis for a high blood pressure condition called primary aldosteronism.

During this clinical trial, you will be asked to eat a high salt diet and a low salt diet for 8 days each. The order in which you eat these high and low salt meals will be randomly determined. In between both study meals, you will eat your usual diet for 6 days. This phase is what our study team called the “wash out phase”. Your health-related information, blood and urine samples be collected for this research study.

This study involves a process called randomization. This means that the type of study meals (high or low salt) you receive first in the study is not chosen by you or the researcher. The order in which you eat your meals will be chosen by a process similar to flipping a coin. If you decide to be in the study, you need to be comfortable not knowing which study meal you will start with first.

There can be risks associated with joining any research study. The type of risk may impact whether you decide to join the study. For this study, some of these risks may include nausea, diarrhea and lightheadedness. More detailed information and more examples of risks will be provided later in this document.

This study may not offer any benefit to you now but may benefit others in the future by simplifying the diagnosis of primary aldosteronism. More information will be provided later in this document.

We expect the amount of time you will participate in the study will be 4 weeks.

You can decide not to be in this study. Alternatives to joining this study include other clinical trials at the University of Michigan.

Even if you decide to join the study now, you are free to leave at any time if you change your mind.

More information about this study continues below.

2. PURPOSE OF THIS STUDY

2.1 Study purpose:

Aldosterone is one of the hormones in the body. It controls fluid levels in the body by controlling sodium and potassium levels in the body. Eating a low or high sodium diet changes the way your genes handle salt, and these changes may be detectable in the blood or urine. The researchers conducting this study are hoping that by detecting these changes in the blood or urine, they may simplify the diagnosis of a sometimes-curable form of high blood pressure, primary aldosteronism. In addition, the research may enable more effective selection of treatments in patients with more common causes of high blood pressure.

3. WHO MAY PARTICIPATE IN THE STUDY

Taking part in this study is completely **voluntary**. You do not have to participate if you don't want to. You may also leave the study at any time. If you leave the study before it is finished, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled.

3.1 Who can take part in this study?

This study is looking for healthy volunteers without high blood pressure between the ages of 21 to 50 years. To participate in the study, you must have no history of hypertension (high blood pressure), chronic kidney disease, heart failure, or diabetes (high blood sugar), you must not have a current urinary tract infection or food allergies and you must be willing to refrain from intense exercises (such as swimming, biking and running). There are also other factors that will be considered as the study doctor determines your eligibility to participate in this study.

3.2 How many people are expected to take part in this study?

The total number of participants may be up to 30.

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study?

Prior to Visit 1:

You will be asked to review the informed consent form and provide an electronic signature if you wish to participate in this clinical trial. After consenting to participate in this study, you will be asked to complete a 3-day food diary and complete questionnaires prior to your Visit 1.

Visit 1:

Your completed online food diary will be provided to the nutritionists during this visit. During this visit we will perform additional tests and collect additional information about you to determine if you are eligible to continue in this study. If you do not qualify based on baseline tests, you will not proceed to the next visit and any information that was collected from you will be stored in a secure manner.

If you choose to participate in this study, we will measure your blood pressure, abdominal diameter, heart rate and other vital signs, and review your medical history and current medications to determine eligibility. All females will have a pregnancy test. We will also perform a physical exam, measure your height, and collect blood and a urine sample during Visit 1. We plan to measure various components of the urine and blood to identify measurable molecules to try to determine whether the receptor of interest is active. For example, we plan to measure messages that tell the body how to make proteins and we may be able to measure all these messages. In addition, we may measure the proteins themselves.

Visit 1 is estimated to take up to 2 hours.

Day before Visit 2:

On the morning before Visit 2, you will start a 24-hour urine collection in a container that we will provide to you. Along with the 24-hour urine container, we will also provide you a discrete tote bag to store the urine container throughout the 24 hours of collection. The tote bag will contain ice packs to keep your urine container cold throughout the day. Alternatively, if you know that you will be at home and you wish to store your urine container in your refrigerator throughout the 24-hour collection, you may do so. It is important to keep your 24-hour urine sample cold for urine analysis.

You will bring the following to Visit 2:

- 24-hour urine in its container and tote bag with its ice packs (which should be cold)

Visit 2:

During Visit 2, we will ask you for the container with your 24-hour urine sample. During this visit, we will provide you your first set of prepared meals made by the University of Michigan Metabolic Kitchen. These meals will be provided to you in a 60-quart cooler with (non-toxic) ice packs. You will consume these prepared meals for 8 days. To prepare for unforeseen circumstances, you will be provided 1 extra day of food.

You may have to return to pick up food during mid-week if your refrigerator doesn't have sufficient storage capacity. If you have any unpleasant effects from the prepared meals, we ask that you contact the study team immediately to discuss them.

Visit 2 is estimated to take 15 minutes.

Visit 2.5:

If your refrigerator has sufficient storage capacity for a 9-day supply of meals at Visit 2, this visit will not occur.

If your refrigerator does not have sufficient storage capacity for a 9-day supply of meals at Visit 2, this visit will occur.

If you wish to pick up the rest of your prepared meals at this time, you will be asked to return to the University of Michigan with the 60-quart cooler containing the cold ice packs that was provided to you at Visit 2. The meals will be provided to you in the cooler with the cold ice packs. We will ask you to consume these prepared meals up until the day of Visit 3. If you have any unpleasant effects from the prepared meals, we ask that you contact the study team immediately to discuss them.

Visit 2.5 is estimated to take 15 minutes.

Day before Visit 3:

On the morning before Visit 3, you will start a 24-hour urine collection in a container that we will provide to you. Along with the 24-hour urine container, we will also provide you a discrete tote bag to store the urine container throughout the 24 hours of collection. The tote bag will contain ice packs to keep your urine container cold throughout the day. Alternatively, if you know that you will be at home and you wish to store your urine container in your refrigerator throughout the 24-hour collection, you may do so. It is important to keep your 24-hour urine sample cold for urine analysis.

You will bring the following to Visit 3:

- 24-hour urine in its container and tote bag with its ice packs (which should be cold)
- Empty 60-quart cooler with its appropriate ice packs

Visit 3:

During Visit 3, we will ask you for the container with your 24-hour urine sample. An additional urine sample and blood will be collected during Visit 3.

Vital signs and abdominal diameter will be measured during this visit. A study team member will inquire about any side affects you experienced during your 8 days on that diet. During this visit, you will return the 60-quart cooler with (non-toxic) ice packs. After this visit, you will begin to consume your usual diet for the next 6 days. We call this the "wash-out period" of the study. No study meals will be provided to you during this visit.

Visit 3 is estimated to take 1 hour.

Day before Visit 4:

On the morning before Visit 4, you will start a 24-hour urine collection in a container that we will provide to you. Along with the 24-hour urine container, we will also provide you a discrete tote bag to store the urine container throughout the 24 hours of collection. The tote bag will contain ice packs to keep your urine container cold throughout the day. Alternatively, if you know that you will be at home and you wish to store your urine container in your refrigerator throughout the 24-hour collection, you may do so. It is important to keep your 24-hour urine sample cold for urine analysis.

You will bring the following to Visit 4:

- 24-hour urine in its container and tote bag with its ice packs (which should be cold)

Visit 4:

During Visit 4, we will ask you for the container with your 24-hour urine sample. In addition, a urine sample and blood samples will be collected during this visit.

Vital signs and abdominal diameter will be measured during this visit. A study team member will inquire about any side affects you experienced during the 8 days on that diet. During this visit, you will be provided with your second set of meals to start the day of Visit 4. These meals will be provided to you in a 60-quart cooler with (non-toxic) ice packs. You will consume these prepared meals for 8 days. To prepare for unforeseen circumstances, you will be provided 1 extra day of food.

If you have any unpleasant effects from the prepared meals, we ask that you contact the study team immediately to discuss them.

Visit 4 is estimated to take 1 hour.

Day of Visit 4.5:

If your refrigerator has sufficient storage capacity for a 9-day supply of meals at Visit 4, this visit will not occur.

If your refrigerator does not have sufficient storage capacity for a 9-day supply of meals at Visit 4, this visit will occur.

If you wish to pick up the rest of your prepared meals at this time, you will be asked to return to the University of Michigan with the 60-quart cooler containing the cold ice packs that was provided to you at Visit 4. The meals will be provided to you in the cooler with the cold ice packs. We will ask you to consume these prepared meals up until the day of Visit 5. If you have any unpleasant effects from the prepared meals, we ask that you contact the study team immediately to discuss them.

Visit 4.5 is estimated to take 15 minutes.

Day before Visit 5:

On the morning before Visit 5, you will start a 24-hour urine collection in a container that we will provide to you. Along with the 24-hour urine container, we will also provide you a discrete tote bag to store the urine container throughout the 24 hours of collection. The tote bag will contain ice packs to keep your urine container cold

throughout the day. Alternatively, if you know that you will be at home and you wish to store your urine container in your refrigerator throughout the 24-hour collection, you may do so. It is important to keep your 24-hour urine sample cold for urine analysis.

You will bring the following to Visit 5:

- 24-hour urine in its container and tote bag with its ice packs (which should be cold)
- Empty 60-quart cooler with its appropriate ice packs

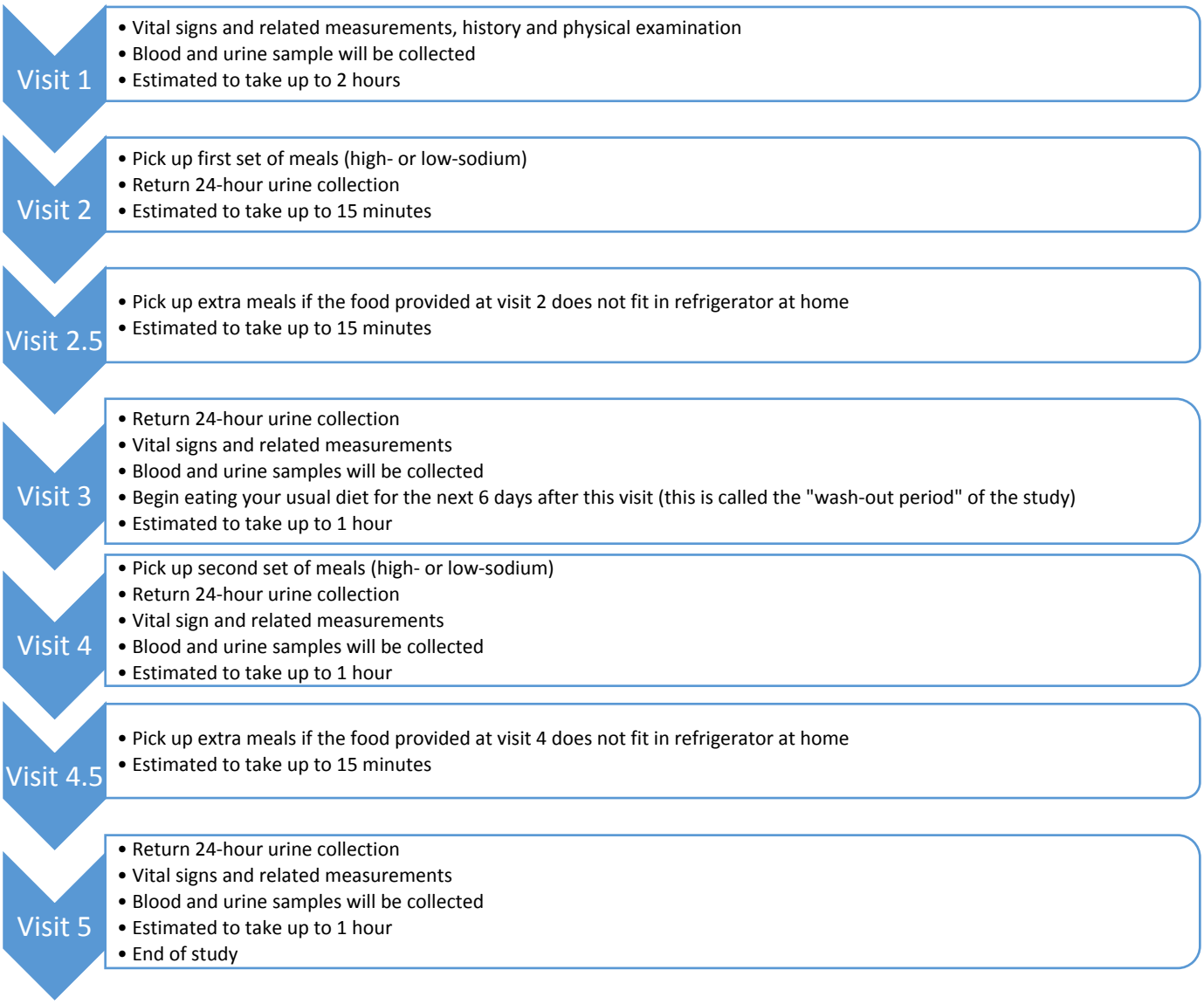
Visit 5:

During Visit 5, we will ask you for the container with your 24-hour urine sample. In addition, a urine sample and blood samples will be collected during this visit.

Vital signs and abdominal diameter will be measured during this visit. A study team member will inquire about any side effects.

Visit 5 is estimated to take 1 hour.

This is the end of study participation.



Schedule of Events:

Study Procedure	Prior to Visit 1	Visit 1	Visit 2	Visit 2.5	Visit 3	Visit 4	Visit 4.5	Visit 5
Consent	X							
3-day Food Diary	X							
Online Questionnaires	X	X	X		X	X		X
Food diary review		X						
Dispensing food			X	X		X	X	
Pregnancy Test		X						
Vital Signs		X			X	X		X
Height		X						
Abdominal Diameter		X			X	X		X
Medication review		X			X	X		X
Medical history		X						
Physical Exam		X						
Adverse event review			X	X	X	X	X	X
Blood Draw		X			X	X		X
Urine sample collection		X			X	X		X
24-hour urine sample return			X		X	X		X
Exhaled breath condensate (RTube) return*			X		X	X		X

*Exhaled breath condensate collection will only be obtained upon the principal investigator's request. This is optional and is not required to participate in the study.

Participant Responsibilities:

As a participant participating in this research study, you have certain responsibilities that may apply to this study, such as ensuring that you arrive at all your scheduled appointments, eating the provided study meals, and reporting any adverse reactions you may have during the study.

OPTIONAL retention of samples for Unspecified Future Research

Besides the information about the main study, the following information is specific to unspecified future use of identifiable data and biospecimens. We would also like your permission to keep some of your blood and urine samples and medical information collected in the main study, so that we may study it in future research. The future research may be similar to this study or may be completely different.

You can take part in the main study even if you decide not to let us keep your blood and urine samples and medical information for future research.

If you give us your permission, we will use your blood samples, urine samples and medical information for future research. Even if you give us permission now to keep some of your blood and urine samples and medical information, you can change your mind later and ask us to destroy it. Keep in mind, however, that once we have analyzed your blood and urine samples, we may not be able to take the information out of our research.

We may share your blood and urine samples and medical information with other researchers, so that they can use it in their research. Their research may be similar to this study or may be completely different. Once we have shared your blood and urine samples and medical information with other researchers, we will not be able to get it back.

Any time private medical information is collected; there is a risk that the information could become known to others. To minimize this risk, the study team will secure any health information collected for the study. Future use of your identifiable data and/or specimens will be conducted in compliance with applicable regulatory requirements.

You will not find out the results of future research on your blood and urine samples. Allowing us to do future research on your blood and urine samples and medical information will not benefit you directly.

With appropriate permissions, your samples and collected information may also be shared with other researchers here, around the world, and with companies.

Your identifiable private information or identifiable biospecimens may be stripped of identifiers and used for future research studies or distributed to another researcher for future research studies without additional informed consent.

Research can lead to new discoveries, such as new tests, drugs, or devices. Researchers, their organizations, and other entities, including companies, may potentially benefit from the use of the data or discoveries. You will not have rights to these discoveries or any proceeds from them.

YOU WILL INDICATE YOUR CHOICE ON THE SIGNATURE PAGE AT THE END.

OPTIONAL Genetic Analysis:

We would also like your permission to study your blood and urine samples and medical information to learn about your genes. The DNA contained in your genes holds the instructions that your body uses to grow and function. Your genes are responsible for your physical features such as eye color, blood type, and how your body breaks down medications. Genes can also be responsible for some medical conditions. Genomic information relates to the structure and function of all of the genetic material in the body. You can still take part in this study even if you decide not to let us sequence your DNA or RNA, whereas analysis of RNA is an essential part of this study.

Blood and urine samples collected during this study will be kept in a laboratory at the University of Michigan for up to 10 years after the end of the study. All personally identifying information will be removed from the samples. They will be identified only by a unique study number.

We may share these samples and research data with other scientists not at the University of Michigan but we will not give them any information that would personally identify you.

Even if you give us permission now to keep some of your blood and urine samples and medical information, you can change your mind later and ask us to destroy it. Keep in mind, however, that once we have analyzed your blood and urine, we may not be able to take the information out of our research. Also, once we have shared some of your blood and urine and medical information with other researchers, we will not be able to get it back.

You will not find out the results of genetic research on your blood and urine. Allowing us to do genetic analysis on your blood and urine and medical information will not benefit you directly.

Parties may benefit financially from future research on your blood and urine and medical information.

YOU WILL INDICATE YOUR CHOICE ON THE SIGNATURE PAGE AT THE END.

4.2 How much of my time will be needed to take part in this study?

Each eligible participant will have 5 study visits at UMHS over the course of approximately 32 days. Visit 1 is expected to be up to 2 hours. Visit 3, 4 and 5 are expected to last one hour. Visit 2 is expected to last 15 minutes. There may be a Visit 2.5 and Visit 4.5, which are expected to last 15 minutes each.

4.3 When will my participation in the study be over?

In addition to the time above, we will collect information from your medical records and complete tests on your samples for another estimated 1 year after your participation.

4.4 What will happen with my information and/or biospecimens used in this study?

Your biospecimens and collected information may be shared with the National Institutes of Health.

With appropriate permissions, your samples and collected information may also be shared with other researchers, here, around the world, and with companies.

Your identifiable private information or identifiable biospecimens may be stripped of identifiers and used for future research studies or distributed to another researcher for future research studies without additional informed consent.

5. INFORMATION ABOUT STUDY RISKS AND BENEFITS

5.1 What risks will I face by taking part in the study? What will the researchers do to protect me against these risks?

Risks associated with a high-salt diet:

Sometimes nausea, diarrhea and/or stomach upset may occur as a result of high sodium diet. In some, blood pressure goes up during a high-salt diet. Whether eating a high-salt diet for a short time could cause a brief increase in blood pressure is unclear. The health risks related to a short-term increase in blood pressure are minimal. We will monitor your blood pressure at the beginning of the study and prior to each diet for safety.

Risk associated with a low-salt diet:

Sometimes, people may feel dizzy or lightheaded and very rarely low blood sodium levels may result. We will check blood sodium levels prior to each diet.

This informed consent document contains 24-hour contact information for the study team. You should contact us if you suspect you are having side effects from the high-salt or low-salt diet.

Side effects from having blood drawn include fainting, discomfort/pain, bruising and bleeding at the site of the needle stick and rarely, an infection. Any complications will be treated immediately.

Risk associated with Genetic Testing:

The federal Genetic Information Nondiscrimination Act (GINA) generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. Under this law:

- Health insurance companies and group health plans may not request your genetic information that we obtain from this research
- 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 we obtain from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment

GINA does not apply to the following groups; however, these groups have policies in place that provide similar protections against discrimination:

- Members of the US Military receiving care through Tricare
- Veterans receiving care through the Veteran's Administration (VA)

- The Indian Health Service
- Federal employees receiving care through the Federal Employees Health Benefits Plans

Any time private medical information is collected; there is a risk that the information could become known to others. To minimize this risk, the study team will secure any health information collected for the study.

As with any research study, there may be additional risks that are unknown or unexpected.

5.2 What happens if I get hurt, become sick, or have other problems as a result of this research?

The researchers have taken steps to minimize the risks of this study. Even so, you may still have problems or side effects, even when the researchers are careful to avoid them. Please tell the researchers listed in Section 10 about any injuries, side effects, or other problems that you have during this study. You should also tell your regular doctors**.**

5.3 If I take part in this study, can I also participate in other studies?

Being in more than one research study at the same time, or even at different times, may increase the risks to you. It may also affect the results of the studies. You should not take part in more than one study without approval from the researchers involved in each study.

5.4 How could I benefit if I take part in this study? How could others benefit?

You may not receive any personal benefits from being in this study. This research may simplify the diagnosis of the most common secondary cause of high blood pressure, primary aldosteronism. In addition, the research may enable more effective selection of treatments in patients with high blood pressure.

5.5 Will the researchers tell me if they learn of new information that could change my willingness to stay in this study?

Yes, the researchers will tell you if they learn of important new information that may change your willingness to stay in this study. If new information is provided to you after you have joined the study, it is possible that you may be asked to sign a new consent form that includes the new information.

6. ALTERNATIVES TO PARTICIPATING IN THE STUDY

6.1 If I decide not to take part in this study, what other options do I have?

As a healthy volunteer, you have the choice to participate or not to participate in the study according to your wishes.

7. ENDING THE STUDY

7.1 If I want to stop participating in the study, what should I do?

You are free to leave the study at any time. If you leave the study before it is finished, there will be no penalty to you. You will not lose any benefits to which you may otherwise be entitled. If you choose to tell the researchers why you are leaving the study, your reasons for leaving may be kept as part of the study record. If you decide to leave the study before it is finished, please tell the person listed in Section 10 “Contact Information” (below). You will be asked to return study materials to University of Michigan.

If you withdraw from the study, no additional data will be collected from you. However, data, blood and urine collected prior to the date of withdrawal can continue to be used. If you withdraw from the study, you may contact us to request a complete withdrawal in which we will not use your previously collected data, blood or urine going forward. You may also request an incomplete withdrawal, in which you may decide to only withdraw from certain aspects of the study (i.e., the Genetic Analysis Sub-study, Unspecified Future Research, blood analysis, urine analysis, etc.). Please note that if data, blood, or urine are already in use for an existing research study, we cannot destroy it or remove it from that study; however, we can remove data or dispose of any remaining blood or urine so it will not be used in any future research studies.

7.2 Could there be any harm to me if I decide to leave the study before it is finished?

There is no harm to you if you decide to leave the study before it is finished.

7.3 Could the researchers take me out of the study even if I want to continue to participate?

Yes. There are many reasons why the researchers may need to end your participation in the study. Some examples are:

- The researcher believes that it is not in your best interest to stay in the study.
- You become ineligible to participate.
- Your condition changes and you need treatment that is not allowed while you are taking part in the study.
- You do not follow instructions from the researchers.
- The study is suspended or canceled.

8. FINANCIAL INFORMATION

8.1 Who will pay for the costs of the study? Will I or my health plan be billed for any costs of the study?

The study will pay for research-related items or services that are provided only because you are in the study. If you are not sure what these are, see Section 4.1 above or ask the researchers for a list. If you get a bill you think is wrong, call the researchers' number listed in Section 10.

You or your health plan will pay for all the things you would have paid for even if you were not in the study, like:

- Health care given during the study as part of your regular care
- Items or services needed to give you study meals
- Monitoring for side effects or other problems
- Deductibles or co-pays for these items or services.

If you do not have a health plan, or if you think your health plan may not cover these costs during the study, please talk to the researchers listed in Section 10 below or call your health plan's medical reviewer.

By signing this form electronically, you do not give up your right to seek payment if you are harmed as a result of being in this study.

8.2 Will I be paid or given anything for taking part in this study?

You will be paid $15 for each of the first four study visits (not including Visit 2.5 and Visit 4.5 if these visits are necessary) that you complete and $60 for completing the fifth study visit. If you withdraw early from the research study, you will retain the payments you have already received and will not be compensated further.

8.3 Who could profit or financially benefit from the study results?

The University of Michigan is an owner and Drs. Byrd and Auchus are named inventors on patents or patent applications. This means, the University of Michigan and Drs. Byrd and Auchus could gain financially from this study. The University of Michigan could be paid licensing fees in the future for tests developed based on this study.

Research can lead to new discoveries, such as new tests, drugs, or devices. Researchers, their organizations, and other entities, including companies, may potentially benefit from the use of the data or discoveries. You will not have rights to these discoveries or any proceeds from them.

9. CONFIDENTIALITY OF SUBJECT RECORDS AND AUTHORIZATION TO RELEASE YOUR PROTECTED HEALTH INFORMATION

The information below describes how the confidentiality of your research records will be protected in this study, and any sub-studies described in this document.

9.1 How will the researchers protect my information?

Your research information will be stored in a locked cabinet and will not be made a part of your regular medical record. However, if the researcher orders any tests, the order and results may become part of your regular medical record.

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 Institute of Health 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, such as child abuse and neglect, or harm 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.

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.

9.2 What protected health information (PHI) about me could be seen by the researchers or by other people? Why? Who might see it?

If you receive any payments for taking part in this study, the University of Michigan accounting department may need your name, address, social security number, payment amount, and related information for tax reporting purposes.

Signing this form gives the researchers your permission to obtain, use, and share information about you for this study, and is required in order for you to take part in the study. Information about you may be obtained from any hospital, doctor, and other health care provider involved in your care, including:

- Hospital/doctor's office records, including test results (X-rays, blood tests, urine tests, etc.)
- All records relating to your condition, the treatment you have received, and your response to the treatment

- Billing information
- Demographic information
- Personal Identifiers

There are many reasons why information about you may be used or seen by the researchers or others during or after this study. Examples include:

- The researchers may need the information to make sure you can take part in the study.
- The researchers may need the information to check your test results or look for side effects.
- University, Food and Drug Administration (FDA) and/or other government officials, auditors, and/or the IRB may need the information to make sure that the study is done in a safe and proper manner.
- Study sponsors or funders, or safety monitors or committees, may need the information to:
    - Make sure the study is done safely and properly
    - Learn more about side effects
    - Analyze the results of the study
- Insurance companies or other organizations may need the information in order to pay your medical bills or other costs of your participation in the study.
- The researchers may need to use the information to create a databank of information about your condition or its treatment.
- Information about your study participation may be included in your regular UMHS medical record.
- If you receive any payments for taking part in this study, the University of Michigan accounting department may need your name, address, social security number, payment amount, and related information for tax reporting purposes.
- Federal or State law may require the study team to give information to government agencies. For example, to prevent harm to you or others, or for public health reasons.

The results of this study could be published in an article, but would not include any information that would let others know who you are.

This trial will be registered and may report results on www.ClinicalTrials.gov, a publicly available registry of clinical trials. You can search this website at any time.

9.3 What happens to information about me after the study is over or if I cancel my permission to use my PHI?

As a rule, the researchers will not continue to use or disclose information about you but will keep it secure until it is destroyed. Sometimes, it may be necessary for information about you to continue to be used or disclosed, even after you have canceled your permission, or the study is over.

Examples of reasons for this include:

- To avoid losing study results that have already included your information
- To provide limited information for research, education, or other activities. (This information would not include your name, social security number, or anything else that could let others know who you are.)
- To help University and government officials make sure that the study was conducted properly

As long as your information is kept within the University of Michigan Health System, it is protected by the Health System's privacy policies. For more information about these policies, ask for a copy of the University of Michigan "Notice of Privacy Practices". This information is also available on the web at

http://www.uofmhealth.org/patient+and+visitor+guide/hipaa. Note that once your information has been shared with others as described under question 9.2, it may no longer be protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA).

9.4 When does my permission to use my PHI expire?

As mentioned in section 4.3, we will collect information from your medical records and complete tests on your samples for another estimated 1 year after your participation. You may cancel your permission to allow us to access your medical records at any time by writing to the researchers listed in Section 10 "Contact Information" (below).

10. CONTACT INFORMATION

10.1 Who can I contact about this study?

Please contact the researchers listed below to:

- Obtain more information about the study
- Ask a question about the study procedures or treatments
- Talk about study-related costs to you or your health plan
- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express a concern about the study

Principal Investigator: J. Brian Byrd, MD, MS
University of Michigan, 5570C MSRB II1150 W. Medical Center Drive, Ann Arbor, MI 48109-5678
Tel: (734) 998-7991 Fax: (855) 230-1379 Email: jbbyrd@med.umich.edu

You may also express a question or concern about a study by contacting the Institutional Review Board listed below:

University of Michigan Medical School Institutional Review Board (IRBMED)
2800 Plymouth Road, Building 520, Room 3214, Ann Arbor, MI 48109-2800
Telephone: 734-763-4768
Fax: 734-763-1234
e-mail: irbmed@umich.edu

If you are concerned about a possible violation of your privacy or concerned about a study you may contact the University of Michigan Health System Compliance Help Line at 1-866-990-0111.

When you call or write about a concern, please provide as much information as possible, including the name of the researcher, the IRBMED number (at the top of this form), and details about the problem. This will help University officials to look into your concern. When reporting a concern, you do not have to give your name unless you want to.

11. RECORD OF INFORMATION PROVIDED

11.1 What documents will be given to me?

Your signature in the next section means that you have received copies of all of the following documents:

- This "Consent to be Part of a Research Study" document. (*Note: In addition to the copy you receive, copies of this document will be stored in a separate confidential research file and may be entered into your regular University of Michigan medical record.)*

12. SIGNATURES

Consent to Participate in the Research Study
I understand the information printed on this form. I have discussed this study, its risks and potential benefits, and my other choices with _____. My questions so far have been answered. I understand that if I have more questions or concerns about the study or my participation as a research participant, I may contact one of the people listed in Section 10 (above). I understand that I will receive a copy of this form at the time I sign it and later upon request. I understand that if my ability to consent for myself changes, I may be asked to re-consent prior to my continued participation in this study.

Print Legal Name: _____

Signature: _____

Date of Signature (mm/dd/yy): _____

Optional: Consent for Participating in a Genetic Analysis Sub-Study
This project involves optional participation in a Genetic Analysis sub-study. I understand that it is my choice whether or not to take part in the sub-study. I understand that if my ability to consent for myself changes, I may be asked to re-consent prior to my continued participation in this study.

Initial your choice below:

_____ Yes, I agree to take part in the optional sub-study.

_____ No, I do not agree to take part in the optional sub-study.

Optional: Consent to Collect for Unspecified Future Research
This project involves the option to allow the study team to keep your identifiable specimens/data for use in future research. I understand that it is my choice whether or not to allow future use of my specimens. I understand that if my ability to consent for myself changes, I may be asked to re-consent prior to my continued participation in this study.

Initial your choice below:

_____ Yes, I agree to let the study team keep my specimens for future research.

_____ No, I do not agree to let the study team keep my specimens for future research.

Principal Investigator or Designee
I have provided this participant with information about this study that I believe to be accurate and complete. The participant indicated that he or she understands the nature of the study, including risks and benefits of participating.

Printed Legal Name: _____

Title: _____

Signature: _____

Date of Signature (mm/dd/yy): _____