

UAB IRB
SAMPLE CONSENT FORM
ENGLISH (with HIPAA Authorization)
VERSION DATE: 06.21.23

Note: It is not possible to address all scenarios for all types of studies conducted by UAB researchers. This sample is designed to assist you in creating your consent form. It is intended to show language preferred by the UAB IRB to address the required elements of informed consent. In many cases, the sample language will need to be modified, deleted, or expanded for the particular study.

Shaded paragraphs like this one are instructions for you, the writer. Do not include them in the consent form you submit. If the instructions indicate that specific language applies to your study, the specific language will be shown below the instructions outside of the shaded paragraph.

Formatting Instructions

- Use 11 or 12 pt font for the consent form.
- Write the consent form in the 2nd person (i.e., you) and keep the pronoun usage consistent throughout.
- Use *Page X of Y* numbering on each page.
- Leave an area approximately 1 inch at the top right of the first page for the IRB approval stamp.

Use understandable, non-technical language at an 8th-grade or lower reading level.

- Readability statistics can be displayed in Microsoft Word. Search Microsoft Office Help for “readability statistics” for further instructions.

DELETE THIS FIRST PAGE OF INFORMATION
IF YOU ARE USING THIS DOCUMENT
TO CREATE YOUR CONSENT FORM

CONSENT FORM TO BE PART OF A RESEARCH STUDY

Title of Research: Evaluation of the Safety and Efficacy of Trimycyn vs. Hydrochlorothiazide in the Treatment of Hypertension

UAB IRB Protocol #: *[Insert UAB IRB Protocol # beginning with IRB-]*

Principal Investigator: John Doe, M.D.

Sponsor: If the study is being sponsored by UAB departmental funds or is unfunded, put the name of the department here (e.g., UAB Department of Medicine). For student research, include the student’s departmental affiliation.

If additional or other support is being provided, include this information with a heading such as **“SUPPORTED BY:”** after the SPONSOR line.

Sponsor: Wise Drug Company, Inc.

If no **Sponsor Protocol #**, remove the heading

Sponsor Protocol #: WDC223

RESEARCH INVOLVING CHILDREN - WHEN TO INSERT “FOR CHILDREN...” BOX:

- When a parent or guardian is providing consent only for a child participant & that child participant will sign *the assent section of the consent form*, do not use “you/your child” throughout the form. Instead, use “you” and insert the following text before the Purpose of the Research section:

For Children (persons under 18 years of age) participating in this study, the term “You” addresses both the participant (“you”) and the parent or legally authorized representative (“your child”).

RESEARCH INVOLVING CHILDREN - WHEN NOT TO INSERT “FOR CHILDREN...” BOX:

- When a parent or guardian is providing consent only for a child participant & that child participant will sign *a separate assent form or will not provide written assent*, use “your child” throughout the form.
- When a parent or guardian is providing consent for both him/herself and a child participant, specify throughout the consent form when you are referring to the parent and when you are referring to the child. This would allow for the use of “you,” “your child,” and “you and your child” throughout the form when appropriate.

[Insert applicable Concise Summary table – see samples in separate document]

General Information	You are being asked 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...
Duration & Visits	You will be in this study for...
Overview of Procedures	This study will include...
Risks	The most common risks include...
Benefits	You may or may not benefit...
Alternatives	If you do not want to take part in the study...

Purpose of the Research Study

- Explain the purpose of the study in nontechnical language.
- Describe why the participant is being asked to join.
- State that the study involves research.
- If drugs or devices are used, indicate whether they are FDA approved or investigational.
- If applicable, define “Pilot”, “Phase I”, “Phase II”, “Phase III”, or “Phase IV” drug study.
- State the total planned number of participants (e.g., individuals, records, specimens) to be enrolled by the UAB investigator, and study-wide for multicenter studies.

We are asking you to take part in a research study. The purpose of this research study is to test how well a new drug lowers blood pressure. The new drug, Trimycin, is investigational and not yet approved by the Food and Drug Administration (FDA). People who enter the study will take either the new drug, Trimycin, or Hydrochlorothiazide (water pill). Hydrochlorothiazide is the FDA approved drug for people to take to lower their blood pressure. More than 200 people in other research studies in the United States have safely used Trimycin. This is a Phase III study. A Phase III study is a research study that tests the effectiveness and monitors side effects of a drug, and compares it to commonly used treatments. This study will enroll 200 participants nationwide. There will be 20 participants enrolled at UAB.

Study Participation & Procedures

- Describe the procedures to be followed, identifying which procedures are for research and which procedures are standard of care.
- Use bulleted lists where necessary to make easier to read.
- Identify if any procedures are experimental.
- Estimate the amount of time involved in study participation.
- If biospecimens (e.g., blood, tissue, body fluids) will be collected as part of this research, describe the collection in this section.
- If identifiable biospecimens will be stored for future research, describe the storage procedures under the “Future Research Use of Identifiable Private Information and/or Identifiable Biospecimens” section.

If you agree to join the study, all of your current blood pressure medicines will be stopped for 1 month. During this time, you will be given pills called placebos. A placebo does not have any active medicine, so it should not have any effect on your blood pressure. However, this placebo might lower your blood pressure. The study staff will watch your blood pressure closely while you are not on any medicine for your blood pressure. Your blood pressure will be watched to make sure it does not rise so high that you need immediate treatment.

- You will come for office visits three times during the first week off your medication.
- You will come for office visits two times per week during Weeks 2, 3, and 4.
- If your blood pressure is in the range required by the study after Week 4, you will be entered into the study. If your blood pressure is not in the range required by the study after Week 4, you will not be entered into the study and will receive standard care for your blood pressure.
- If you are entered and complete the entire study, you will be in the study for 6 months.

- If randomization is part of the study, explain what randomization is and how it is done.
- If the study is blinded, explain what blinded means.
- If the study involves a placebo,
 - define placebo (not as *treatment* or *medication*; see paragraph above that begins “*If you enter the study...*”)

You will be randomly picked (like the flip of a coin) by a computer to receive either Trimycin or Hydrochlorothiazide. You will take the study drug you receive once a day by mouth. This is a double-blind study. This means neither you nor your doctors will know which study drug you are taking. If necessary, the doctor can find out which you are taking.

These tests will be made during the study:

- lab blood tests & urine tests
- weight measures
- resting electrocardiogram (measures the electrical activity of the heart)
- heart rate
- blood pressure

You will be asked to come back to the clinic for 20 weekly visits after you begin the study drug. At each visit you will be asked how you are feeling on the study drug and about any side effects.

Drug Screening: If drug screening is part of the study, include a statement that addresses how long participants must not have used drugs. For example:

If you have used any illicit (street) drug(s) within *[insert appropriate time frame]*, we ask that you not participate in this study.

HIV Testing: If HIV testing is part of the study, individuals whose test results are associated with personal identifiers must be informed of their own test results and provided the opportunity to receive appropriate counseling before and after the testing.

Reportable Diseases: If testing for other reportable diseases is part of the study, individuals will be informed of the results and told where to obtain counseling and referred to their primary care physician or the state health department.

Incidental Findings: If research-only imaging studies are part of the study, address whether or not the images will be read for incidental findings. If the images will not be read for incidental findings, include the following language:

Incidental Findings:

We are performing imaging solely for the research purposes described above. It is not a clinical scan intended for diagnostic or therapeutic purposes. Under no circumstance will the investigator, research staff, or imaging staff interpret the scan as normal or abnormal. They are unable to make any medical comments about your scan. The scan will not be looked at or read for any healthcare treatment or diagnostic purpose. If you want your scan to be reviewed by a physician so the physician can look for medical issues, you can request a copy of your scan. We will provide an electronic copy at no charge.

Additional Information:

For research that involves the collection of identifiable private information **and/or** identifiable biospecimens, include a statement indicating either:

- The identifiers may be removed from the identifiable private information or identifiable biospecimens, and then that de-identified private information or de-identified biospecimens could be used for future research without additional informed consent.
- OR-
- The private information or biospecimens collected as part of the research will not be used or distributed for future research studies even if identifiers are removed.

For example, you may state:

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. **This is only when there are no identifiers associated with the data or biospecimens.**

For research that involves the use of biospecimens, include a statement indicating:

- whether biospecimens may be used for commercial profit, and
- whether the participant will share in that profit

For example, you may state:

The biospecimens obtained from you for this research, which may or may not include your identifiable private information, may be used for commercial profit. There are no plans to provide financial compensation to you should this occur.

For research expected to generate clinically relevant results, include a statement indicating:

- whether the clinical results (including individual research results) will be returned to the participant, and
- if results will be returned, under what conditions

For example, you may include:

The clinical results (including individual research results) will not be returned to you.

For research that involves whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen), include a statement indicating:

- the research will (if known) or might include whole genome sequencing

For example, you may state:

This research involves whole genome sequencing, which is the process of mapping all of an individual's genes.

Risks and Discomforts

- Include any foreseeable risks or discomforts to the participant (e.g., physical, social, financial, loss of employability, reputation, and breach of confidentiality).
- When possible, quantify the risks involved (e.g., "*frequent, common, occasional, rare;*", or percentages).
- Use bulleted lists where necessary to make easier to read.
- If the study involves a placebo,
 - include the risks of the placebo group and what complications may result
 - describe the precautions that will be taken to protect the participant during this time
- Do not include risks or discomforts associated with drugs or interventions that are not being administered or performed as part of this study.

You may have some side effects from taking the study drugs.

The side effects of Trimycin are:

- headaches
- feeling sleepy

- feeling tired

About forty percent (40%) of people who take Trimycin have reported feeling drowsy and tired. About twenty percent (20%) of people who take Trimycin have headaches.

The side effects of Hydrochlorothiazide are:

- low blood potassium
- rise in blood uric acid which can cause crystals to form in the joints
- rise in blood sugar
- lowering of red and white blood cells

About eighty percent (80%) of people who take Hydrochlorothiazide have these problems.

There may also be risks that are unknown at this time. You will be given more information if other risks are found.

Randomization: If randomization is part of the study, ensure the risks of all study arms are described in detail in this section even if the procedures in those arms would be standard of care if the participant was not in the study. Also include a statement on risks of randomization. For example:

You will be assigned to a group by chance, which may prove to be less effective or to have more side effects than the other study group or alternatives.

Information for Women of Childbearing Potential, Nursing Mothers, and/or Men Capable of Fathering a Child

If women of childbearing potential, nursing mothers, and/or men capable of fathering a child are included in the study, address the precautions that should be taken before, during, and/or after participating in the study. List the specific acceptable methods of contraception (if appropriate to the study). Use only the information that is applicable to the study population. For example:

We do not know if the study drug will affect mother's milk or an unborn fetus. Therefore, breastfeeding and pregnant women are not allowed to take part in the study. If you are pregnant or become pregnant, there may be risks to the embryo or fetus that are unknown at this time. Women who can become pregnant must take a pregnancy test before the start of the study.

You should not father a child while on this study as the treatment may indirectly affect an unborn child. If you are sexually active and are at risk of causing a pregnancy, you and your female partner(s) must use a birth control method to avoid pregnancy that works well or you must not have sex.

Unless you cannot have children because of surgery or other medical reasons, you must have been using an effective form of birth control before you start the study. You must also agree to continue to use an effective form of birth control for 6 months after taking the study drug. Effective birth control includes birth control pills, patch, IUD, condom, sponge, diaphragm with spermicide, abstinence, or any other method prescribed by your physician.

Benefits

- State any potential benefits to the participant or to others that may reasonably be expected from the research.

- Do not overstate benefits.
- If there is no potential for direct benefit to the participant, that should also be stated.
- **Do not include** medication, treatment, devices, or compensation information.

You may not benefit directly from taking part in this study. However, this study may help us better understand how to treat high blood pressure in the future.

- **Randomization:** If randomization is part of the study, include a statement on the benefits of randomization.

You will be assigned to a group by chance, which may prove to have more or less benefits than the other study group.

Alternatives

- Include appropriate alternative procedures or courses of treatment that may be advantageous to the participant.
- One alternative may be to not participate in the study.

There are many other drugs that are used to treat high blood pressure. Some examples of these drugs are Betasan, Enapror, and Ditserin. The investigator or research staff will discuss these other drugs with you.

Confidentiality and Authorization to Use and Disclose Information for Research Purposes

The Confidentiality and Authorization section can only be altered where indicated. You can add sponsor language as long as it is not redundant and it is in the appropriate subsection.

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.

Include following subsection for research **not at JCDH:**

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.

- **Medical Record not at JCDH:** If the consent form will be placed in the participant's medical record **at UAB Health System and/or Children's of Alabama**, include the following (4 paragraphs):

Your consent form will be placed in your medical record at UAB Health System or Children's of Alabama. This may include either a paper medical record or electronic medical record (EMR). An EMR is an electronic version of a paper medical record of your care within this health system. Your EMR may indicate that you are on a clinical trial and provide the name and contact information for the principal investigator.

If you are receiving care or have received care within this health system (outpatient or inpatient), results of research tests or procedures (i.e. laboratory tests, imaging studies and clinical procedures) may be placed in your existing medical record.

If you have never received care within this health system (outpatient or inpatient), a medical record will be created for you to maintain results of research tests or procedures.

All information within your medical record can be viewed by individuals authorized to access the record.

Include following subsection for research at JCDH:

What protected health information may be used and/or given to others?

All medical information related to your participation in this study. This may include your name, medical record number, date of birth, dates of service, etc.; any past, present, and future history related to this research study, examinations, laboratory results, imaging studies and reports and treatments; 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.

- Medical Record at JCDH: If the JCDH HIPAA Authorization form will be placed in the participant's medical record at Jefferson County Department of Health, include the following (2 paragraphs):

Your JCDH HIPAA Authorization form for this study will be placed in your electronic medical record (EMR) at Jefferson County Department of Health. Your EMR may indicate that you are on a clinical trial and provide the name and contact information for the principal investigator.

All medical information related to your participation in the study within your medical record can be viewed by individuals authorized to access the record.

Continuation of Confidentiality and Authorization section (include for all):

- ClinicalTrials.gov: If the study will be registered on ClinicalTrials.gov, include the following language (if similar language is not already included in the Sponsor/Lead Site's template language):

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 website 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

• Include applicable information only for the italicized portion of the two bullets below:

- 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, *University of Alabama Health Services Foundation, Children's of Alabama, Eye Foundation Hospital, and the Jefferson County Department of Health*, as necessary for their operations; the UAB IRB and its staff
- the billing offices of *UAB and UAB Health Systems affiliates and/or Children's of Alabama* and its billing agents

Continuation of Confidentiality and Authorization section (include for all):

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.

- Certificate of Confidentiality: If your study is NIH-funded or you have or plan to obtain a Certificate of Confidentiality, include the following:

This research *[is/will be]* 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 *[insert Sponsor]* 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 of *[list what will be reported, 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.

Reportable Diseases/Conditions: If testing for reportable diseases is part of the study, include the following language specifying what reportable diseases are being tested and that positive results will be reported to the county or state health department:

As part of this study, you will be tested for *[insert disease]*. If the results show that you are positive for *[insert disease]*, the study staff will tell you the results. The study staff will be required to give your name to the Alabama Department of Public Health if you test positive because this is the law.

Screening for Drugs, Observations of Abusive Behavior: If drug screening is part of the study or there will be questions about abusive behavior (e.g., child or elder abuse or neglect, or harm to self) include the following language:

Information obtained during the course of the study which, in the opinion of the investigator(s), suggests that you may be at significant risk of harm to yourself or others will be reportable to a third party in the interest of protecting the rights and welfare of those at potential risk.

Genetic Research: If genetic testing is part of the study, describe the protections provided to the participant under GINA. Include the following language (if similar language is not already included in the Sponsor/Lead Site's template language):

A federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and some employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:

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

Be aware that this federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance, nor does it protect you against genetic discrimination by all employers.

Continuation of Confidentiality and Authorization section:

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.

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 doctor. 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.

Voluntary Participation and Withdrawal

Whether or not you take part in this 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.

- Include the consequences of a participant's decision to withdraw from the research.
- Include procedures for how the participant should withdraw. (An example paragraph is below; however, you should revise as applicable to your study.)

You are free to withdraw from this study at any time. Your choice to leave the study will not affect your relationship with this institution. However, you should return to see the study doctor for safety reasons so you can be taken off the study drug and referred for follow-up care. Contact the study doctor if you want to withdraw from the study.

- If applicable, include anticipated circumstances under which the PI without regard to the participant's consent may terminate the participant's involvement. (An example paragraph is below; however, you should revise as applicable to your study.)

You may be removed from the study without your consent if the sponsor ends the study, if the study drug is approved by the FDA, if the study doctor decides it is not in the best interest of your health, or if you are not following the study rules.

Students/Employees: If students or employees of UAB are recruited to participate in the study, include the following language:

If you are a UAB student or employee, taking part in this research is not a part of your UAB 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 UAB. You will not be offered or receive any special consideration if you take part in this research.

Cost of Participation

- If any costs to the participant or the participant's health insurance might result from the research (e.g., for tests, drugs, biologics, devices, or copayments), describe those costs. Include information about any financial assistance that may be available, such as how to consult a social worker.
- If there is no cost to the participant, this should be stated.

There will be no cost to you for taking part in this study. All drugs, exams, and medical care related to this study will be provided to you at no cost during the 6-month study period.

If standard medical care may be provided during the study include the following language:

The costs of your standard medical care will be billed to you and/or your insurance company in the usual manner.

Medicare Advantage: If participants may be enrolled in Medicare Advantage and will have study related services billed to their Medicare Advantage insurance, include the following language:

If you have questions about clinical trial billing at a UAB Health System location, contact the Office of Clinical Billing Review at fap@uab.edu. For more on FAP requirements, go to [FAP - Site Minder Processes](#). If you have questions about clinical trial billing for studies conducted at Children's of Alabama, contact Pam Barlow at pam.barlow@childrensal.org or 558-2452.

If you are in Medicare Advantage (Medicare managed care plan), you should contact someone at your plan before you start a clinical trial. They can provide more information about additional costs you could incur from participating in clinical trials.

Category B Medical Devices: If a Category B medical device is used in the study, include the following language:

Your insurance company may or may not pay for the device(s) used in this study. Your insurance company may decline to cover these types of devices. Therefore, it is very important that you provide your current health insurance information to UAB and that you check with your insurance company about the costs of participation.

Payment for Participation

- Note: Payment may not be based upon successful completion of the study.
- Specify the amount of compensation a participant will receive for participating OR specify there is no compensation for participation.
- If applicable, include the payment schedule.
- Describe prorated payments for participants who withdraw before the end of the study.
- If children are involved, specify whether the child or parent is being paid.
- If there is payment for participation, the last sentence, "Ask the study staff about the method of payment that will be used for this study (e.g., check, cash, gift card, direct deposit)" should always be included instead of specifying the payment method in the consent form.

You will be paid \$10 for each study visit, including the placebo phase of the study. If you withdraw from the study, you will be paid \$10 for each study visit made to the clinic. Payments will be made after 3 months and 6 months if you complete the entire study. The total payment you may receive is \$290. If you do not finish the entire study, you will be paid at the time you decide to stop taking part in the study. Ask the study staff about the method of payment that will be used for this study (e.g., check, cash, gift card, direct deposit).

If a participant is to earn \$600 or more in a calendar year from their participation in research, include the following language:

You are responsible for paying any state, federal, Social Security or other taxes on the payments you receive. You will receive a form 1099 in January of the year following your participation in this study. This form is also sent to the IRS to report any money paid to you. No taxes are kept from your payment.

Payment for Research-Related Injuries

Include this section only if the research involves (a) greater than minimal risk or (b) procedures or interventions that could result in harm or injury.

If the section is to be included, include the UAB statement below.

- Include other locations (e.g., Jefferson County Department of Health), if applicable.

UAB has not provided for any payment if you are harmed as a result of taking part in this study. If such harm occurs, treatment will be provided. However, this treatment will not be provided free of charge.

If the research is sponsored, include the UAB statement below that addresses whether or not the sponsor(s) will provide compensation for research-related injuries.

- For sponsored research where the sponsor(s) **will not pay** for compensation to injured research participants or pay for medical treatment of research-related injuries, include the names of all sponsors after “UAB”.

UAB and *[insert Sponsor]* have not provided for any payment if you are harmed as a result of taking part in this study. If such harm occurs, treatment will be provided. However, this treatment will not be provided free of charge.

- For sponsored research where the sponsor(s) **will pay** for either compensation or treatment for research-related injuries, include the specific language provided by the sponsor(s) regarding injury compensation. NOTE: The IRB must be provided with “sponsor verification” in the form of a letter signed by the sponsor(s) with the same wording given in the consent form, a model consent form included in the protocol and listed in the Table of Contents of the protocol with the same wording, or in the contract or agreement. Do not submit a copy of the indemnification letter as the verification. Include information regarding what medical treatment will consist of if injury occurs and where further information may be obtained.

New Findings

Indicate that significant new findings developed during the course of the research that may relate to the participant’s willingness to continue participation will be provided to the participant by the principal investigator or his/her staff.

You will be told by the study doctor or the study staff if new information becomes available that might affect your choice to stay in the study.

Optional

[Insert information about optional portions here. Provide initial lines to agree/disagree at each decision point.]

Future Research Use of Identifiable Private Information and/or Identifiable Biospecimens *[this subsection should be indented under the Optional section header]*

If there will be future research use of identifiable private information and/or identifiable biospecimens (research not specifically defined in the study), address the following points and include lines for participants to initial (do not use checkboxes):

- What identifiable private information and/or identifiable biospecimens will be collected and how they are collected
- Whether the identifiable private information and/or identifiable biospecimens will be shared with other investigators and if so, whether they will be shared outside UAB
- Whether the participant may be re-contacted for additional consent for future research
- How long the identifiable private information and/or identifiable biospecimens be stored
- Any foreseeable risks or benefits to participants in the collection, storage, and future research use of identifiable private information and/or identifiable biospecimens
- Potential for commercial use of the identifiable biospecimens
- How to withdraw consent for future research use

**If the study is a database or repository, include this information in the Explanation of Procedures section and do not create a separate “Future Research Use of Identifiable Private Information and/or Identifiable Biospecimens” section. Initial lines would not be necessary if that is the case.

The following is an example of the language that may be used (if similar language is not already included in the Sponsor/Lead Site’s template language):

This study is collecting private information (data containing personal information) and biospecimens (*[specify blood/specimen]*). We would like your permission to keep your private information and biospecimens collected in this study for future research. 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.

Your private information and biospecimens will be identifiable. Results of any future research will not be given to you or your doctor.

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

If you give us permission now to keep your identifiable private information and identifiable 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.

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

[Indicate additional risks the future research may pose and describe efforts to minimize them.] Future research use of your identifiable private information and identifiable biospecimens will be conducted in compliance with applicable regulatory requirements.

You will not find out the results of the future research. Allowing us to do future research on your identifiable private information and identifiable biospecimens will not benefit you directly.

The identifiable private information and identifiable biospecimens used for future research may be used for commercial profit. There are no plans to provide financial compensation to you should this occur.

Initial your choice below:

I agree to allow my identifiable private information and identifiable biospecimens to be kept and used for future research on *[specify disease or disorder]*.

I do not agree to allow my identifiable private information and identifiable biospecimens to be kept and used for future research.

Data Sharing [e.g., Genomic Data Sharing (GDS), NIH Data Management & Sharing (DMS), NSF Data Management Plan (DMP), etc. [this subsection should be indented under the Optional section header]

There is an increasing expectation for investigators to share data, including genomic/genetic data, as a condition of funding and publication. For some studies, investigators may be required to obtain participants' consent for their genomic and phenotypic data to be used for future research purposes and to be shared broadly. The consent form should include an explanation about whether participants' individual-level data will be shared through unrestricted- or controlled-access repositories. For studies with specific data sharing requirements (e.g., NIH, NSF), please refer to the specific policies governing those requirements.

The following paragraph is an example of the language that may be used (if similar language is not already included in the Sponsor/Lead Site's template language):

Your data (including [specify as applicable: e.g., information collected about your health, individual genes, and medical conditions]) may be shared broadly in a coded form for future research or analysis. Researchers are often required to share data for funding and publication purposes to advance science. We may give this data about you to other researchers or companies not at UAB, including to a *[specify public or controlled access]* government health research database. We will not give them your name, address, phone number, or any other identifiable information. You will not receive the results of any future studies or analyses performed on your data *[if applicable, describe any rare instance where research results would be returned]*.

If the data will be shared with **unrestricted**-access databases, include the following paragraph:

Your information may be put in unrestricted-access databases. This means the information is publicly available and anyone can use the database.. The only health information included will be whether you had *[specify disease or disorder]* or not. This public information will not be labeled with your name or other information that could be used to easily identify you.

If the data will be shared with **controlled**-access databases, include the following paragraph:

Your information may be put in controlled-access databases. This means only researchers who apply for and get permission to use the information for a specific research project will be able to access the information. Your information stored in these databases will not include any identifying information and will only include a code. Only certain study personnel for this study at UAB will have access to information that could link the code to your identifiable information. Researchers approved to access information in the controlled-access database will agree not to attempt to identify you.

Include the following paragraphs for all GDS (or other sharing of genomic/genetic data):

Risks: A risk of sharing your genomic data is that someone could link the information stored in the databases back to you. If your information suggested something serious about your health, it could be misused. For example, it could be used to make it harder for you to get or keep a job or insurance or be used to discriminate against you or your family. Federal law generally makes it illegal for health insurance companies, group health plans, and employers to discriminate against you based on your genetic information. There may also be other unknown risks.

Benefits: There is no direct benefit to you from sharing your genomic data. Allowing researchers to use your data may lead to a better understanding of how genes affect health. This may help other people in the future.

If applicable, include the following:

- An explanation that a participant can withdraw his/her data from the repository. If this option is available, include a statement that the data already distributed for approved research use cannot be retrieved.

Initial your choice below:

___ I agree for my relevant study data, such as health information, to be shared broadly in a coded form for future research or analysis.

___ I do not agree for my relevant study data, such as health information, to be shared broadly in a coded form for future research or analysis.

Questions

- Include the name of the Principal Investigator and his/her contact number for participants to contact regarding the research and research-related injuries.
- Include afterhours contact information.
- Include the names of additional contact personnel, if applicable.

If you have any questions, concerns, or complaints about the research or a research-related injury including available treatments, please contact the study doctor. You may contact Dr. *[specify PI]* at *[specify PI's phone number with area code]* or after hours by paging him at *[specify number]*.

Include the UAB Office of the IRB contact information:

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 toll free at 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

- Should be in second person (i.e., you).

- The signature only indicates agreement to participate; do not include other attestations (e.g., I have had all my questions answered, etc.).

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

It is not possible to address all scenarios for signature requirements that may be needed for various types of research. These instructions and samples are designed to assist you in the preparation of the Signatures section. In many cases, the Signatures section will need to be customized for the particular study population.

- The requirements for signature lines depend upon the consent process described in the Human Subjects Protocol.
- Each signature-date line included in the Signatures section, as applicable to the research, must be signed and dated.
- All signatures must appear on the same page, but that page does not need to be a separate page with no other information.
- Each person who signs the consent form must include the date of his/her signature.
- If the research involves children (i.e., individuals younger than 18 years of age for research conducted in the state of Alabama), see "Children" under General Information in the IRB Guidebook and see Example Signatures for Research Involving Children, below.
- If the research involves pregnant women, see "Pregnant Women, Fetuses, Neonates" under General Information in the IRB Guidebook.
- A signature-date line for the participant must be included. The acceptable options are shown and described below.

Option 1

	Date
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Option 2

Legally Authorized Representatives (LAR)

- If the research proposes to obtain consent from the participant **or** the LAR, add "(or Legally Authorized Representative)" after "Signature of Participant."
- If the research proposes to obtain consent from the participant **and** the LAR, include a separate signature-date line for each person.

	Date
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Option 3

	Date
--	------

	Date
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Option 4

Signature of Participant 14 Years of Age and Older Date

Signature of Parent or Guardian Date

- The UAB IRB usually recommends the following:
 - Waiver of assent needs to be documented for participants under 7 years of age, but these participants should be included in the consent process if possible.
 - A separate assent form should be prepared for use with, and to document the assent of, participants who are 7-13 years old.
 - Participants 14-17 years old will document their assent by signing the main consent form.
- If the IRB determines the permission of only one parent or guardian is necessary, only include one line for "Signature of Parent or Guardian".

Other Signature Lines:

Person Obtaining Consent

- All persons who obtain informed consent must be listed in the ePortfolio.
- If the Principal Investigator always obtains consent, this line would always be signed by the Principal Investigator.

Signature of Person Obtaining Consent Date

Witness (ONLY IF APPLICABLE)

Include this line **ONLY** if you will enroll illiterate participants and must have a witness, if you will use a Short Form and must have a witness, -or- have justification for adding this line written in your Human Subjects Protocol.

Signature of Witness Date

Reviewed by (ONLY IF APPLICABLE)

Include this line **only** if the ePortfolio specifies that the principal investigator will not obtain informed consent but will only review signed consent documents.

Reviewed by:

Signature of Principal Investigator Reviewing Consent Document Date

Waiver of Assent

Include this section if assent of participants may be waived.

Waiver of Assent

The assent of _____ (name of child/minor) was waived because of:
Age _____ Maturity _____ Psychological state of the child _____