**FORMAT:**

**Black Text in size 14 font indicates a new section of the consent**

**Text that is required to be VERBATIM will be indicated**

**Red Text: Indicates the elements of consent that are mandated by the federal government**

**Blue text: Indicates UH mandated language**

**Purple text: Indicates information that needs to be in the consent only if it applies to the study**

**Grey text: Is suggested language that may be used in your consent**

**Required formatting of the Informed Consent Document**

* **The entire document must be submitted on the UH template**
* **Font must be size 12 or larger**
* **Font must all be in black**
* **Pages should be number 1 of XX**
* **Should be single spaced**
* **Version number is listed as required for approval letter**
* **Version date should be updated each time**
* **Pronoun use needs to be consistent throughout the document – second person is preferred but first person is allowed**
* **Language cannot be coercive**
* **Please do not submit a tracked change document**

# Key Information: The following is a short summary of this study to help you decide whether or not to be a part of this study. More detailed information is listed later on in this form.

# Why am I being invited to take part in a research study?

### Elements to include:

### The circumstance or condition that makes subjects eligible for the research

* + **Suggested Language:** We invite you to take part in a research study because \_\_\_\_\_\_\_\_\_\_\_\_\_.
	+ **Suggested Language:** You are being asked to participate in this research study because [you are a normal volunteer, [AND/OR] you have (a certain illness or condition) [AND/OR] you are scheduled to undergo (a standard of care procedure) [AND/OR] you are part of a (some organization) from which the research study is seeking information].

# Things I should know about a research study

* Someone will explain this research study to you.
* Whether or not you take part is up to you.
* You can choose not to take part.
* You can agree to take part and later change your mind.
* Your decision will not be held against you.
* You can ask all the questions you want before you decide.

# Introduction/Purpose

### Elements to include:

### Tell the subject the purpose of the research.

* + **Suggested Language:** The purpose of this research study is \_\_\_\_\_\_.

### Explain the background of the research problem.

### Explain any potential benefits to others.

### How many subjects will be enrolled

### Suggested Language: You will be one of [INSERT NUMBER OF PARTICIPANTS] participants enrolled in this study which includes [INSERT NUMBER OF SITES] sites in [INSERT LOCATIONS SUCH AS US, CANADA, ENGLAND, ETC]. Approximately [INSERT NUMBER OF PARTICIPANTS] participants from this facility will participate in this study.

### For Drug and Device Studies: FDA phase of a study and indication of whether the drug is experimental or approved but being used for an unapproved indication

### Suggested Language: The [INSERT NAME OF DRUG AND/OR DEVICE] being studied is experimental, which means that the U.S. Food and Drug Administration (FDA) has not approved it for use.

OR

### Suggested Language: The [DRUG/DEVICE] being studied in this study is called [INSERT NAME OF DRUG AND/OR DEVICE] and has been approved by the USFDA for certain uses; however, this study is testing [INSERT NAME OF DRUG AND/OR DEVICE] to treat [INSERT NAME OF DISEASE/CONDITION] therefore [INSERT NAME OF DRUG AND/OR DEVICE] is considered experimental in this study.

# Key Study Procedures

### Elements to include:

### Include an estimate of how long participation will last

### Suggested Language: We expect that you will be in this research study for \_\_\_\_\_\_\_\_ [*hours/days/months/weeks/years, until a certain event*].

### Include a high level summary of the procedures that will be done. For example: You will be given an investigational drug and asked to be asked to come for 3 study visits. You will give a total of 3 blood samples and fill out questionnaires asking about how you feel.

### Suggested Language: You will be asked to \_\_\_\_\_\_\_\_\_

## Include Language: More detailed information about the study procedures can be found under “Detailed Study Procedures”

# Key Risks

### Elements to include:

### This beginning section of the consent form should identify the most important risks, e.g., emotional distress resulting from a series of questions in a social-behavioral research project or similar to the information that a physician might deliver in the clinical context in telling a patient how sick, e.g., the chemotherapy drugs will make them, but with a particular emphasis on how those risks are changed by participating in the study

### Include language: More detailed information about the risks of this study can be found under “Detailed Risks”

# Benefits

### Elements to include:

### This beginning section of the consent form should identify one or more likely benefits resulting from participation in the study; in doing so, you should not overemphasize the benefits. If you need to discuss benefits in additional detail, add an additional section later in the consent document

## Exclude any statements indicating that the subject may benefit from closer monitoring of their condition or free treatment.

## Do not include benefits that presume a positive answer to the study question.

## Compensation and reimbursement should not be discussed in this section

### If there are benefits to participation: First describe any direct benefits to the subject, then any benefits to others. If benefits from participation may not continue after the research has ended, describe them here.

### Suggested Language:We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.

### If there are no benefits to participation: Describe any benefits to others. Monetary reimbursement for participation is not a benefit.

### Suggested Language:There are no benefits to you from your taking part in this research. We cannot promise any benefits to others from your taking part in this research. However, possible benefits to others include \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.

### For research involving prisoners

### Suggested Language: Taking part in this research study will not improve your housing or correctional program assignments. Your taking part in this research study will not improve your chance of parole or release.

# Alternatives to Study Participation

### Elements to include:

* **If there are alternatives other than participating: List alternatives procedures. For student subject pools describe alternatives for course credit. For clinical trials describe the options that you would normally offer patient. If applicable, include supportive care as an option**
	+ **Suggested Language:** Participation in research is completely voluntary. You can decide to participate or not to participate. Instead of being in this research study, your choices may include:
* **If there are no alternatives other than participating:**
	+ **Suggested Language:** Participation in research is completely voluntary. You can decide to participate or not to participate.Your alternative to participating in this research study is to not participate.

# Detailed Information: The following is more detailed information about this study in addition to the information listed above.

# Detailed Study Procedures:

## Begin with the total duration of the study and the number of study visits involved (if there is more than one)

* + **Suggested Language:** As a participant in this study, you will be asked to come to the [INDICATION LOCATION]. Your participation in this study will last for [LENGTH OF TIME] and will involve [X] visits

## A clear description of what will happen and the expectations of the subject should they choose to partake in this research study

## A clear and simple description of the research related study procedures the participants will partake in listed in chronological order. Please be sure to specify if any of the procedures are experimental.

* + As procedures are described, indicate the amount of time it will take to complete that procedure or study visit **Suggested Language**: This part of the study, (or this procedure) (this visit) will last approximately….

When numerous visits or procedures are involved, they should be outlined using visit subheadings (e.g., Visit 1 [Pre-Screening], Visit 2 [Randomization] etc) or in table format

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Example Table:** | Pre-Screening | Visit 1 | Visit 2 | Visit 3 | Six week Follow up |
| Estimated time requirement | 2 hours | 1 hour | 20 minutes | 1 hour | 10 minutes |
| Data Collection | X |  |  |  |  |
| Study Procedure 1 |  | X | X | X |  |
| Study Procedure 2 |  | X |  | X |  |
| Study Procedure 3 |  | X |  | X |  |
| Phone Call Questionnaire |  |  |  |  | x |

### Blood Draws:

* + Include the amount in teaspoons, tablespoons, or ounces (1 teaspoon=5 ml, 1 tablespoon=15 ml, 1 ounce=30 ml) that will occur each time
	+ The amount of times blood will be drawn
	+ The total amount of blood collected by end of study
	+ **Suggested Language:** You will have (amount) of blood withdrawn (number of times drawn, and frequency). The total amount of blood drawn for the entire study will be (amount).

### Screening:

* + **Suggested Language:** At this visit, the following screening procedures will be performed to determine if you can take part in this study.

### Baseline/Washout:

* + Include medications that will have to be stopped prior to starting the study.
	+ **Suggested Language:** [X weeks/days] before your first visit you will have to stop taking the following medication

### Randomization/Study Intervention: Explain and clearly describe the groups into which subjects are randomized. If the study involves a placebo or control group, also explain that (select appropriate option).

Randomize

(A process will randomly put you in a study group)

Group 2

(Study group)

You agree to take part in the study

Group 1

 (Usual approach group)

* **Suggested Language:** If you participate in this study, you will be assigned to a study group by chance using a process similar to the flip of a coin. This process is called randomization. Neither you nor study staff will select the group to which you will be assigned and the study staff will not be able to tell you which group you are in. However, this information can be obtained if you have a medical emergency.
* **Suggested Language:** If you participate in this study, you will be assigned to a study group by chance using a process similar to the flip of a coin. This process is called randomization. Neither you nor study staff will select the group to which you will be assigned. The study staff will know which group you are in but will not tell you. This information can be given to you if you have a medical emergency.

### Drug studies using a placebo: Describe the different groups

* + **Suggested Language**: A placebo is an inactive substance containing no medication.
	+ **Suggested Language**: Subjects in the control group will receive no investigational treatment but will be monitored by study staff.
	+ **Suggested Language**: Subjects assigned to the control group will receive the standard treatment.

### Follow up Procedures: Include number of follow-up visits (and/or phone calls), frequency, description of what will occur and time involved

# Detailed Risks

## Formatting suggestions regarding how to present risks:

### Use subheadings when there are multiple elements involving risks, (i.e., list the risks of each drug, device, or study procedure separately.)

### Only list the risks of research related procedures. However, some protocols intimately link investigational procedures with standard of care procedures. If standard of care risks are appropriate to include, clearly identify these as risks applying equally to standard treatment.

### The risk section should be ordered based on the likelihood of risks or the severity of risks. If the frequency is known for common risks, state the percent.

### Animal study risk findings should normally be excluded from the consent form, but may be selectively included when relevant to the subject consent process. For example, when existing data for human studies are not relevant or informative, if the investigational drug or device has had limited exposure in humans, or if a new risk has been identified based on animal data.

### Emotional and psychological risks should also be addressed in the consent form.

## This section should include foreseeable risks and discomforts that may occur as a result of participating in the research.

## The risks section should open with a clear statement of whether the study is associated with risk. Suggested Language: Your participation in this study does not involve any physical risk to you. OR Your participation in this study may involve the following risks . . .

## Include the risk of breach of confidentiality Suggested Language: There is a risk of breach of confidentiality which means that someone who is not listed in this form might view your data either by accident or from malicious actions they take to hack the data. We are protecting against this by only storing information that can be directly linked to you on UH computers, in password protected files which are behind firewalls.

## Only include the risks of the research related procedures (if possible)

### Risk to Pregnancy: If a subject is or may become pregnant during the course of the research, a statement must be included to inform subjects that the particular treatment or procedure may involve risks to the subject, or to the embryo or fetus, which are currently unforeseeable. Suggested Language: Participation in this study may involve risks that are currently unforeseeable to the embryo or fetus due to the nature of this research. If any new risks become known in the future, you will be informed of them.

### If there is the possible risk of emotional discomfort from dealing with sensitive issues or answering a questionnaire, this risk should also be included. Suggested Language: Some of the questions may be upsetting, or you may feel uncomfortable answering them. If you do not wish to answer a question, you may skip it and go to the next question.

### For studies involving a blood draw: Suggested Language: The insertion of the needle to draw blood is painful; however, this discomfort is brief. For most people, needle punctures to get blood samples to not cause any serious problems; however, they may cause bleeding, bruising, discomfort, infections, dizziness, or fainting.

### For studies involving placebo, discontinuation of current medication, or a washout period, include a statement that the subject’s condition may worsen while taking part in this study. Suggested Language: Your condition may not improve or may worsen while you are taking part in this study.

### If the risks of an investigational drug are not fully established, or a novel medication combination is being tested, include this statement. Suggested Language: We cannot predict all risks or potential side effects.

### If the study includes outpatient medications the following should be included. Suggested Language: The study drug must be taken only by you. It must be kept in a safe place out of reach of children and other people who cannot read well or understand that they should not take it.

### If the study includes radiation exposure for research purposes, an understandable statement about the dose should be included. Sample paragraphs for radiation exposure are available at: <http://www.safety.duke.edu/radsafety/consents/consents.htm> Chest x-ray example: If you take part in this research, you will have one or more medical x-ray studies. These x-rays involve a small amount of radiation. To give you an idea about how much radiation you will get, we will compare it to the amounts you encounter in your daily life. There is radiation that naturally occurs from space and from rocks in the soil. This natural radiation is greater at higher altitudes. Participating in this research gives you about the same amount of radiation as you would get from [INSERT INFORMATION REGARDING RADIATION EXPOSURE, E.G., FROM DUKE WEBSITE]. This radiation dose is what you will receive from this study only and does not include any exposure you may have received or will receive from other tests.

### If HIV testing is a requirement for study participation, include this statement. If HIV testing is an exclusion from participation in the study, modify the paragraph to reflect this. Suggested Language: As part of this protocol, you will be tested for HIV (human immunodeficiency virus, which is the virus that causes the acquired immunodeficiency syndrome [AIDS]). You will be notified of the results of the testing, and counseled as to the meaning of the results, whether they are positive or negative. If the test indicates that you are infected with HIV, you will receive additional counseling about the significance for your medical care and possible risks to other people. We are required to report all positive results to the Ohio State Board of Health. The test results will be kept confidential to the extent permissible under the law. If you do not want to be tested for HIV, then you should not agree to participate in this study.

# Consequences of Withdrawing or being discontinued from the Research – if applicable to study

* If there are consequences related to a subject’s decision to withdraw from the research, or being withdrawn from the research, this section should include a statement describing the consequences; and the procedures for the orderly termination of participation by the subject.

**Suggested Language**: If you decide to stop for any reason, it is important to let the study doctor know as soon as possible so you can stop safely. If you stop, you can decide whether or not to let the study doctor continue to provide your medical information to the organization running the study.

The study doctor will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

The study doctor may take you out of the study:

* If your health changes and the study is no longer in your best interest
* If new information becomes available
* If you do not follow the study requirements
* If the study is stopped by the sponsor, Institutional Review Board (IRB) or FDA.

**Suggested Language:** If you withdraw from the study prior to its completion, you will be asked to return all study medication and, for your safety, come in for a final clinical visit in order to (*specify exactly what will happen at this visit, i.e. questionnaire, interview, blood tests, duration, etc.)*

**Suggested Language:** If you withdraw from the study prior to its completion, you will be asked to return the [INSERT NAME OF STUDY DEVICE] and, for your safety, come in for a final clinical visit in order to (*specify exactly what will happen at this visit, i.e. questionnaire, interview, blood tests, duration, etc.)*

# Reproductive Health/Sexual Activity

## If subjects should avoid pregnancy while participating in the study, the following section should be edited to apply to the specifics of the study. If the reproductive risks apply only to one gender, the paragraph should be appropriately modified.

## If a study drug might interact with any birth control methods, additional clarification should be provided and alternative birth control methods suggested.

### Suggested Language for Men and Women: The effect of \_\_\_\_\_\_\_\_ on human sperm and eggs has not been studied. The effects on the developing child of using \_\_\_\_\_\_\_\_\_ during pregnancy and the risk of birth defects are unknown. (If data exists about the safety of the drug during pregnancy include it.) Therefore, both men and women should not attempt pregnancy and women should not be pregnant or breast-feeding while participating in this study (or for XX amount of time after completing the study). If sexually active, both men and women should use an effective method of birth control while taking the study drug. Barrier contraceptives (condoms or diaphragm) with spermicide, intrauterine devices, hormonal contraceptives (Depo-Provera, Norplant), oral contraceptive pills, and complete abstinence are examples of effective methods. If you or your partner become pregnant while taking the study drug, it is important that you notify your study nurse/physician immediately. You may be required to stop the study drug at which time other treatment options will be discussed with you.

### Suggested Language for Women: Being a part of this study while pregnant may expose the unborn child to significant risks. Therefore, pregnant women will be excluded from the study. If you are a woman of childbearing potential, a pregnancy test will be done, and it must be negative before you can enter this study. If you are sexually active, you must agree to use appropriate contraceptive measures during the study. Medically acceptable contraceptives include: (1) surgical sterilization, (2) approved hormonal contraceptives such as birth control pills, (3) barrier methods (such as a condom or diaphragm) used with a spermicide, or (4) an intrauterine device (IUD). If you do become pregnant during this study, you must inform your study physician immediately.

### Suggested Language for Men: The treatment used in this study could affect your sperm and could potentially harm a child that you may father while on this study. If you are sexually active, you must agree to use a medically acceptable form of birth control in order to be in this study. Medically acceptable contraceptives include: (1) surgical sterilization, or a (2) condom used with a spermicide.

## If you are enrolling minors and doing pregnancy testing, please include the following language VERBATIM: If you have a positive pregnancy test during a study visit and you are younger than 14 years of age the study team is required to tell you, your parent or legal guardian and the Department of Children and Family Services. If you are 14 years of age or older and tell the study team that you are pregnant or have a positive pregnancy test during a study visit, the study team must give this information to your parent/legal guardian if they ask. The study team can help you share this information with your parent or legal guardian.

# Financial Information

## This section should open with one of the following statements:

### There is no cost to you or your insurance for participation in this study.

### Your participation in this study will involve cost to you. You or your insurance company will be responsible for payment of . . . , and all other medical care that would normally be part of the treatment of . . . The study will pay for . . .

### The study will pay for all procedures/devices/drugs that are directly associated with this research study. This includes …. Procedures or drugs that are considered standard of care will be the responsibility of you or your insurance company. This includes ….

## Costs that are research-related and those that are standard of care should be clearly identified.

## If the research procedures/devices/drugs used in the study might not be covered by a subject’s insurance, a statement should be added that advises subjects to contact their insurance provider to determine their level of coverage.

## If the study is using a device, include who is responsible for the cost of the device if it is lost, stolen or broken.

## Specify if subjects will be paid for their participation in the study.

### Payment for specific aspects of the study (i.e. drugs, devices, visits, testing, transportation, and standard care) should be made clear to the subject.

### Suggested Language: You will receive \_\_\_\_\_\_\_ dollars for your participation in this research study. It will be paid *(*specify the method of payment and when*).* If you withdraw from the study, you [will/won’t] be paid for the portions that you completed, depending upon…

### Suggested Language: You will not be paid for your participation in this study

## Specify if subjects will be reimbursed for their participation in the study.

### Suggested Language: You will be reimbursed for [INSERT WHAT SUBJECTS ARE GOING TO BE REIMBURSED FOR such as: transportation expenses, parking etc…].

### Suggested Language: You will not be reimbursed for [INSERT WHAT SUBJECTS ARE EXPECTED TO PAY FOR such as: transportation expenses, parking etc…].

## If study includes any billable patient services (except pediatrics) please include the following information VERBATIM:

**Notice for Managed Care (Medicare Advantage Plan) Beneficiaries**

Certain services provided to you as a participant in a clinical trial are allowable to be billed to, and paid by, your medical insurance.  These services are referred to as “covered” clinical trial services.  If you have a Medicare Advantage Plan as part of your medical insurance, the Centers for Medicare & Medicaid Services (CMS) require that traditional Medicare will be billed for those services.  When this occurs, you will remain responsible for paying the coinsurance and deductibles according your Medicare Advantage Plan.  Your Medicare Advantage Plan should cover any associated cost share related to Medicare.  Please speak with a financial counselor to understand what the specific financial impact will be for you associated with participating in this clinical trial.

## If financial compensation is provided, the following must be in the consent form VERBATIM: To receive payment you must agree to complete a W-9 form which requires you to provide an address and social security number to the accounting department. This payment to you may be considered taxable income by the IRS. You will be issued a 1099-Misc form only if payment exceeds $600 from all studies in which you are participating, in a fiscal year.

# Research-Related Injury

## [REQUIRED IF THE TRIAL IS INTERVENTIONAL AND/OR THERE IS A CHANCE THAT A SUBJECT MAY BE INJURED AS A DIRECT RESULT OF STUDY PROCEDURES.]

* **Please identify who a subject should contact in the case of a study related injury**

## ONLY ONE VERSION OF THE LANGUAGE BELOW MAY BE UTILIZED. THIS LANGUAGE MAY NOT BE CHANGED OR REVISED. ADDITIONAL LANGUAGE RELATED TO DISCUSSION OF PAYMENT FOR RESEARCH RELATED INJURY MAY NOT BE ADDED TO OTHER SECTIONS OF THE CONSENT FORM. YOU MUST ENSURE THAT THE OPTION CHOSEN IS CONSISTENT WITH THE CLINCAL TRIAL AGREEMENT.

### Option #1 Use this language VERBATIM if any payment for injury will be provided – you may only change the blue text

In the event you suffer a research related injury as a result of being in this study, University Hospitals will provide appropriate medical treatment for such injury in a timely manner. Provision of such medical treatment does not imply any negligence or other wrongdoing on the part of University Hospitals or any of the physicians or other personnel involved in the study. If you believe that you have been injured as a result of participating in the study, please immediately contact your University Hospitals study doctor even if you may have already been seen or treated by another doctor. If you are seen or treated by a doctor other than the study doctor, you should inform such doctor that you are in this study and, if possible, take this document with you as it may help such doctor treat you.

If you have a private medical insurance plan, your plan may be billed for the costs of treatment as appropriate. If there are any costs that are not paid by your medical insurance plan, the Sponsor has agreed to pay research related injury treatment costs, provided certain coverage eligibility criteria are met. You will still be responsible for any co-payments, co-insurance or deductibles required by your medial insurance plan.

If you are covered by Medicare, Medicaid HMO plans or any other governmental healthcare insurance or if you are not covered by a health insurance plan, the Sponsor has agreed to pay the costs of treatment of a research related injury, provided certain criteria are met. If you have Medicare or another governmental insurance plan, the Sponsor may request your Social Security number, as the Sponsor may have mandatory reporting requirements under the Medicare Mandatory Reporting provisions.

The specifics of Sponsor coverage criteria for this study can be provided upon request by contacting your study doctor.

University Hospitals has not set aside any money to pay you or to pay for your treatment if you suffer a research related injury as a result of being in the study. There are no plans for University Hospitals to provide other forms of compensation (such as lost wages, pain and suffering, or other direct or indirect losses) to you for research related injuries. You are not waiving any legal rights by signing this form, including the right to seek compensation for an injury. Further information about research-related injuries is available by contacting the University Hospitals Cleveland Medical Center’s Research Subject Rights phone line at (216) 983-4979.

### Option #2 Use this language VERBATIM if no payment for injury will be provided

If injury occurs as a result of your involvement in this research, medical treatment is available from University Hospitals or another medical facility but you/your medical insurance will be responsible for the cost of this treatment.  A research injury is an injury that happens as a result of taking part in this research study.  If you are injured by a medical treatment or procedure that you would have received even if you weren’t in the study, that is not considered a “research injury”. There are no plans for payment of medical expenses or other payments, including lost wages, for any research related injury.  To help avoid injury, it is very important to follow all study directions.

# Clinically Relevant Research Results:

When applicable, include whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions; and for research involving biospecimens

* **Suggested language:** Most tests done on samples in research studies are only for research and have no clear meaning for health care. If the research with your identifiable information or samples gives results that do have meaning for your health, the researchers [will/will not] contact you to let you know what they have found. If the researchers return genetic test results to you, it may be because they think you could have a health risk and want to recommend that the test should be re-done by a certified clinical laboratory to check the results. If this happens, then you may want to get a second test from a certified clinical laboratory, consult your own doctor, or get professional genetic counseling. You may have to pay for those additional services yourself.

**Future contact for other research projects:**

* **UH encourages study teams to use this section in order to track consent to contact for future research studies. Please use the below language as an example**

# Contact for Future Research

Our study team may have additional research studies in the future. We would like your permission to contact you in the future if we think you could be a potential participant in one of our studies. Please check one of the boxes below that indicates your choice to be contacted for future research.

* Please contact me by \_\_\_\_\_\_\_\_\_ for future research opportunities.

❑ Please do not contact me for future research opportunities.

# Genetics Studies

## Genetic research studies may create medical, psychosocial, and economic risks to human subjects and their relatives. Genetic studies present a wide range of issues and the consent form needs to be individualized for each study.

* After January 25, 2015, all NIH funding applicants are expected to include a data sharing plan consistent with the Genomic Data Sharing (GDS) Policy. NIH expects investigators who intend to use research or clinical specimens collected or cell lines created after January 25, 2015 to generate human genomic data may only do so with informed consent for future research use and broad sharing of the data from those specimens, even if they are de-identified. NIH-designated data repositories will not accept human genomic data derived from specimens or cell lines collected or created after January 25, 2015 unless informed consent has been provided for future research use and broad sharing.

## In studies involving genetic testing, the following issues may need to be addressed:

* Will test results be given to the participant?
* Will disease risk be quantified, including the limits on certainty of the testing?
* Will any change in a family relationship be disclosed, such as mistaken paternity?
* Does the subject or family member have the option not to know the results? How will this decision be recorded?
* Could other clinically relevant information be uncovered by the study? How will disclosure of this added information occur?
* Do any limitations exist on the subject’s right to withdraw from the research, withdraw data, and/or withdraw DNA?
* Is the subject permitted to participate in the study while refusing to have genetic testing?
* Will DNA be stored or shared? If shared, will the subject’s identity be known by the new recipient investigator?
* Will the subject be contacted in the future by the investigator to obtain updated clinical information?
* How can the subject opt out of any distribution or subsequent use of his/her genetic material if they sign the consent and participate in the study?
* Whether the research will (if known) or might include 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
	+ In lay terms you will need to state if research (chose one):
		- 1.) Will include whole genome sequencing with the intent to generate the genome or exome sequence of that specimen
		- 2.) May include whole genome sequencing with the intent to generate the genome or exome sequence of that specimen
		- 3.) Will not include whole genome sequencing with the intent to generate the genome or exome sequence of that specimen
	+ Suggested Language: Research testing on your sample [will/will not] include whole genome sequencing. This means we will map your entire genetic code. If you have questions about this ask the study staff.

### If genetic studies are optional for study participants, include a yes/no option.

You can participate in this research study even if you do not want to have a sample taken for DNA(gene) studies. Please indicate below your choice.

 ❑ Yes, I want to have a sample for the DNA (gene) studies.

 ❑ No, I do not want to participate in the DNA (gene) studies.

* **For studies where guidance about how to handle future genetic results could be important the following paragraph should be added to the previous paragraph.**

### In family genetic studies the issues of paternity should be discussed.

* + **Suggested Language:** When the DNA is examined from members of a family paternity can be determined. It is the policy of University Hospitals Health System that paternity results are not disclosed to study participants. The only exception to this is if a court or other legal authority requires disclosure.

### For studies that focus on identifying abnormal genes that are clinically significant.

Through this research, we may find that you have an abnormal gene which puts you at risk for developing [INSERT DISEASE OR CONDITION] at some time in the future. These results may also provide information about your entire family. Some people involved in genetic studies have felt anxious about the possibility of carrying an abnormal gene that places them at risk or that can be passed on to their children. If you have these feelings at any time during the study, you may contact the investigator(s) who will arrange for you to speak with a genetic counselor.

and/or

The information obtained as a result of your participation in this research will not be included in your medical record. Information from which you may be personally identified will be maintained in a confidential, locked file at [INSERT LOCATION] and will not be disclosed to third parties except with your permission or as may be required by law.

### If samples will be submitted to the National GWAS Repository for Genome Wide Association Studies, or to any of the NIH-designated genomics data repositories use the following VERBATIM:

In addition to the use described here, coded information about your DNA (phenotype and genotype) may also be submitted to one of several national databases for genetic information maintained under the supervision of the National Institutes of Health (NIH). As part of this database these coded samples will be shared with other investigators for future approved research purposes. Neither NIH nor other researchers using the coded information will be able to identify you directly. Although your genetic information is unique to you, there is a very small chance someone could trace it back to you, and this small risk will likely get larger in the future.

If, at a future date you wish to withdraw your consent to allow use of your DNA information in this NIH GWAS database, you can contact [INSERT LOCAL OR COORDINATING RESEARCHER CONTACT- NOT NIH GWAS] to withdraw your information. This will remove your information for any future research. Any research that was conducted with your data prior to this request will be unable to be withdrawn and may still be utilized.

It is unlikely at this stage that any future use of your DNA would give the researchers any information about you or your specific condition. Therefore, there are no plans for you to receive any individual results from any future tests. If a future researchers find something very important about you or your condition, they may contact this study investigator with your code number and the results. The study investigator would then contact you regarding the results.

# CLINICAL TRIAL INFORMATION

## Any study that is considered an “[applicable clinical trial](http://clinicaltrials.gov/ct2/info/results)” by the FDA and required to be registered in the Clinicaltrials.gov database must also include the following paragraph VERBATIM: U.S. NATIONAL INSTITUTES OF HEALTH (NIH) CLINICAL TRIAL DATABASE: A description of this clinical trial will be available on <http:///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 to find out information about the trial and basic results.

* ***Please check to see if your trial is applicable by going to the following link:*** [*https://prsinfo.clinicaltrials.gov/ACT\_Checklist.pdf*](https://prsinfo.clinicaltrials.gov/ACT_Checklist.pdf)

# Student/Employee Rights

## This section is required if students or employees of the institution (Case or UH) are included as research subjects. Suggested Language: Choosing not to participate or withdrawing from this study will not affect your employment or class standing, nor will the results be shared with your supervisor.

**Termination of Participation**

## This section should include any anticipated circumstances under which the subject’s participation may be terminated by the investigator without regard to the subject’s consent. Include this section if there are conditions for involuntary withdrawal (sponsor closes study, etc.). Suggested Language: Your participation in this study may be discontinued by the sponsor or investigator without your consent if [specify conditions such as: failure to comply with protocol, taking your medications correctly etc].

# Confidentiality – REQUIRED SECTION – This is not the same thing as HIPAA Authorization

## This section should include a statement describing the extent to which confidentiality of records identifying the subject will be maintained. If any data have identifiers removed and use a code to link to the identifiers, describe who has access to the codes and how the codes are kept secure.

## Centralized data collection or registries

* Also indicate if the results will be stored by an identifier or code, and protections in place for privacy of records.)
	+ Suggested Language: The results of your examinations will be collected in a centralized computer or data registry at (name the facility and give the location – the city and state).

## Use of Data and/or Samples:

* **Storage of tissues for the purposes of this study**
	+ **Suggested Language: After tissues are collected for study they will be identified by a study number and not by your name or identifying information.**
* **If identifiable private information or identifiable specimens will be collected during the research, add one of the following statements:**
	+ **Required Language: If identifiers are removed from your identifiable private information or identifiable samples that are collected during this research, that information or those samples could be used for future research studies or distributed to another investigator for future research studies without your additional informed consent.**

**OR**

* + **Required Language: Your information or samples that are collected as part of this research will not be used or distributed for future research studies, even if all of your identifiers are removed.**
* **If commercial potential exists from the use of data, tissues, blood, or DNA, the following information should be included.**
	+ **Suggested Language: Your information and samples (both identifiable and de-identified) may be used to create products or to deliver services, including some that may be sold and/or make money for others. If this happens, there are no plans [or replace with plans when using identifiable information/samples] to tell you, or to pay you, or to give any compensation to you or your family.**
* **If you would like to potentially store identifiable data or identifiable samples for future use, please include the following sections and be sure to address issues of secure storage elsewhere in the consent. Please note that the security of data and samples must be maintained as you would for any study related data.**
	+ **Future use of Identifiable Samples**

**It is possible that the identifiable sample(s) collected during this research project may be helpful for other project(s) as well. If this is the case, we would like to ask your permission to use your identifiable samples in these project(s). \*\*Please specifically address what elements of PHI will be retained (name, DOB, etc).\*\***

* My identifiable samples may be used for this project only.
* My identifiable samples may be used for future research.
	+ **Future use of Identifiable Data**

**It is possible that some of the identifiable data collected during this research project may be helpful for other project(s) as well. If this is the case, we would like to ask your permission to use your identifiable data in these project(s). Please check the box that correctly indicates your choice. \*\*Please specifically address what elements of PHI will be retained (name, DOB, etc).\*\***

* My identifiable data may be used for this project only.
* My identifiable data may be used for future research.

## Dealing with video or audio records upon completion of the study

### UHCMC policy is that recordings are destroyed after data analysis is complete unless extended use is authorized by the subject. If recordings will not be destroyed, justify this in the protocol and specify the use in the consent form.

### Suggested Language: We may publish or present photographs, audio recordings, and videos of you [INCLUDING/NOT INCLUDING - specify one] your face. No other personal information about you will be included in the presentation. All videotapes, audiotapes, and photographs will be destroyed at the end of the study. You will be asked to sign a separate consent form called GM-23 that allows us to use this information.

## When subjects are likely to reveal reportable activities

### In studies in which researchers think it is likely that subjects will reveal actions that the researchers are obligated to report to authorities, these statements, if applicable, should be added explaining that such circumstances may arise. Suggested Language: If the study personnel find evidence that suggests that you have been physically or sexually abused, they are required by law to report this to local law authorities.

### Suggested Language: The only exception to this promise of confidentiality is that we are legally obligated to report evidence of child abuse or neglect.

### Suggested Language: We will not ask you about child abuse, but if you tell the interviewers about child abuse they are required by law to report your name to the state authorities.

## When subjects are likely to reveal illegal activities but acquiring a Certificate of Confidentiality would be excessive or is not possible

### Suggested Language: In this study, you will be asked about illegal activities [specify]. The researchers will keep information about you as confidential as possible, but complete confidentiality cannot be guaranteed. On rare occasion, courts have subpoenaed research records.

## When Certificate of Confidentiality has been obtained

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.

**Use the following language as applicable**

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 AGENCY] 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.

**Language such as the following should be included if researcher intends to disclose  information covered by a Certificate, such as potential child abuse, or intent to hurt self or others in response to specific federal, state, or local laws.**

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].

Language such as the following should be included if researcher intends to disclose information covered by a Certificate, with the consent of research participants.

The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document [restate what will be disclosed, such as including research data in the medical record].

# Privacy of Protected Health Information – REQUIRED SECTION - VERBATIM

The Health Insurance Portability & Accountability Act (HIPAA) is a Federal law that helps to protect the privacy of your health information and to whom this information may be shared within and outside of University Hospitals. This Authorization form is specifically for a research study entitled “ [***insert name of research study***]” and will tell you what health information (called Protected Health Information or PHI) will be collected for this research study, who will see your PHI and in what ways they can use the information. In order for the Principal Investigator, [***insert Principal Investigator’s name***], and the research study staff to collect and use your PHI, you must sign this authorization form. You will receive a copy of this signed Authorization for your records. If you do not sign this form, you may not join this study. Your decision to allow the use and disclosure of your PHI is voluntary and will have no impact on your treatment at University Hospitals. By signing this form, you are allowing the researchers for this study to use and disclose your PHI in the manner described below.

Generally the Principal Investigator and study staff at University Hospitals and Case Western Reserve University who are working on this research project will know that you are in a research study and will see and use your PHI. The researchers working on this study will collect the following PHI about you: [***list in a specific and meaningful fashion the PHI that will be collected for the purposes of this research***]. This PHI will be used to [***insert a description of each specific purpose of the research study in lay terms***]. Your access to your PHI may be limited during the study to protect the study results.

Your PHI may also be shared with the following groups/persons associated with this research study or involved in the review of research: [***insert specific names of ALL entities and persons by whom PHI will be disclosed or used (e.g., sponsor, CRO, other sites/ investigators). If PHI will not be disclosed, indicate such***]; other staff from the Principal Investigator’s medical practice group; University Hospitals, including the Center for Clinical Research and the Law Department; Government representatives or Federal agencies, when required by law.

Your permission to use and disclose your PHI does not expire. However, you have the right to change your mind at any time and revoke your authorization. If you revoke your authorization, the researchers will continue to use the information that they previously collected, but they will not collect any additional information. Also, if you revoke your authorization you may no longer be able to participate in the research study. To revoke your permission, you must do so in writing by sending a letter to [***insert name and mailing address for Principal Investigator***]; If you have a complaint or concerns about the privacy of your health information, you may also write to the UH Privacy Officer, Management Service Center, 3605 Warrensville Center, MSC 9105, Shaker Heights, OH 44122 or to the Federal Department of Health and Human Services (DHHS) at DHHS Regional Manager, Office of Civil Rights, US Department of Health and Human Services Government Center, JF Kennedy Federal Building, Room 1875, Boston, MA 02203. Complaints should be sent within 180 days of finding out about the problem.

The researchers and staff agree to protect your health information by using and disclosing it only as permitted by you in this Authorization and as directed by state and Federal law. University Hospitals is committed to protecting your confidentiality. Please understand that once your PHI has been disclosed to anyone outside of University Hospitals, there is a risk that your PHI may no longer be protected; however other Federal and State laws may provide continued protection of your information.

# Summary of your rights as a participant in a research study – REQUIRED SECTION

Your participation in this research study is voluntary. Refusing to participate will not alter your usual health care or involve any penalty or loss of benefits to which you are otherwise entitled. If you decide to join the study, you may withdraw at any time and for any reason without penalty or loss of benefits. If information generated from this study is published or presented, your identity will not be revealed. In the event new information becomes available that may affect the risks or benefits associated with this study or your willingness to participate in it, you will be notified so that you can decide whether or not to continue participating. If you experience physical injury or illness as a result of participating in this research study, medical care is available at University Hospitals Cleveland Medical Center (UHCMC) or elsewhere; however, UHCMC has no plans to provide free care or compensation for lost wages.

# Disclosure of your study records – REQUIRED SECTION

Efforts will be made to keep the personal information in your research record private and confidential, but absolute confidentiality cannot be guaranteed. The University Hospitals Cleveland Medical Center Institutional Review Board may review your study records. If this study is regulated by the Food and Drug Administration (FDA), there is a possibility that the FDA might inspect your records. In addition, for treatment studies, the study sponsor and possibly foreign regulatory agencies may also review your records. If your records are reviewed your identity could become known.

# Contact information – REQUIRED SECTION

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ has described to you what is going to be done, the risks, hazards, and benefits involved. The Principal Investigator [INSERT NAME OF PRINCIPAL INVESTIGATOR] can also be contacted at [INSERT PI CONTACT NUMBER]. If you have any questions, concerns or complaints about the study in the future, you may also contact them later.

If the researchers cannot be reached, or if you would like to talk to someone other than the researcher(s) about; concerns regarding the study; research participant’s rights; research- related injury; or other human subject issues, please call the University Hospitals Cleveland Medical Center’s Research Subject Rights phone line at (216) 983-4979 or write to: The Associate Chief Scientific Officer, The Center for Clinical Research, University Hospitals Cleveland Medical Center, 11100 Euclid Avenue, Lakeside 1400, Cleveland, Ohio, 44106-7061.

# Signature - REQUIRED SECTION

Signing below indicates that you have been informed about the research study in which you voluntarily agree to participate; that you have asked any questions about the study that you may have; and that the information given to you has permitted you to make a fully informed and free decision about your participation in the study. By signing this consent form, you do not waive any legal rights, and the investigator(s) or sponsor(s) are not relieved of any liability they may have. A copy of this consent form will be provided to you.

[INSTRUCTIONS FOR SIGNATURE BLOCK: THERE ARE SEVERAL DIFFERENT SIGNATURE BLOCKS THAT CAN BE UTILIZED. ONCE YOU FIND THE SIGNATURE BLOCK THAT APPLIES TO YOUR STUDY, DELETE THE OTHER SIGNATURE BLOCKS, EXCEPT FOR THE “*Study personnel”* BLOCK. BE SURE TO DELETE THE BLUE TEXT AS WELL]

USE BOTH A SUBJECT BLOCK AND THE STUDY PERSONNEL BLOCK

[USE THIS FOR STUDIES ENROLLING ADULTS]

|  |  |
| --- | --- |
| x |  |
| Signature of Participant Date |
| x |  |
| Printed Name of Participant |

[USE THIS FOR STUDIES ENROLLING DECISIONALLY IMPAIRED ADULTS]

|  |  |
| --- | --- |
| x |  |
| Signature of Participant Date |
| x |  |
| Printed Name of Participant |
| *If participant does not have the capacity to consent and protocol is approved for inclusion* |
| x |  |
| Signature of Legally Authorized Representative (LAR) or Next of Kin Date |
| x |  |
| Printed name of Legally Authorized Representative (LAR) or Next of Kin  |
| If Next of Kin, please mark ONE relationship from list below (in decending order of priority):  |
|  | Spouse |  | Adult Child |  | Custodial Parent |  | Adult Sibling |  | Adult relative (related by blood or adoption) |

[USE THIS FOR STUDIES ENROLLING MINORS where the IRB has determined ONE PARENT SIGNATURE is sufficient]

|  |  |
| --- | --- |
| x |  |
| Signature of Participant Date |
| x |  |
| Printed name of minor if used to obtain assent |
| x |  |
| Signature of Parent/Legal Guardian Date |
| x |  |
| Printed name of Parent/Legal Guardian  |
| x |  |
| If Legal Guardian, indicate relationship to child |

[USE THIS FOR STUDIES ENROLLING MINORS where the IRB has determined TWO PARENT SIGNATURE are required]

|  |  |
| --- | --- |
| x |  |
| Signature of Participant Date |
| x |  |
| Printed name of minor if used to obtain assent |
| x |  |
| Signature of Parent/Legal Guardian Date |
| x |  |
| Printed name of Parent/Legal Guardian  |
| x |  |
| If Legal Guardian, indicate relationship to child |
| x |  |
| Signature of second parent Date |
| x |  |
| Printed name of second parent |
| If unable to obtain second parent signature, indicate why: (*mark one*) |
|  | Deceased |  | Unknown |  | Legally incompetent |  | No legal responsibility for care/custody of child |

[USE THIS WHEN A WITNESS IS INCLUDEDED IN THE CONSENTING PROCESS (Common examples include: Inclusion of illiterate individuals, non-english speaking individuals or individuals who cannot physically sign but are able to provide informed consent.)]

|  |  |
| --- | --- |
| x |  |
| Signature of Witness Date |
| x |  |
| Printed Name of Witness |

*Study personnel(only individuals designated on the checklist may obtain consent)*

|  |  |
| --- | --- |
| x |  |
| Signature of person obtaining informed consent Date |
| x |  |
| Printed name of person obtaining informed consent  |
|  |  |