Consent Form

Record ID _____

StudyID: _____

Consent form for UCI-GREGoR: [pmgrcid]

First Name: [firstname]
Last name: [lastname]
Date of Birth: [date_of_birth]

UCI-GREGoR Informed Consent

The Informed Consent Form for the UCI-GREGoR study is below.

University of California, Irvine (UCI)

Department of Pediatrics

1003 Health Sciences Road

Suite 308

Irvine, CA 92617

(949) 824-4090

Consent/Parental Permission to Participate in a Clinical Research Study and Authorization to Use Protected Health Information

STUDY TITLE: Pediatric Mendelian Genomics Research Center

PRINCIPAL INVESTIGATOR: Eric Vilain, MD, PhD, University of California, Irvine

Throughout this document, "You" always refers to the person (you or your child) who takes part in the study.

SUMMARY AND KEY INFORMATION

We are inviting you to be part of a research study at the University of California, Irvine (UCI). Taking part in this study is your choice. You can choose to take part or you can choose not to take part in this study. You also can change your mind about participating at any time. Whatever choice you make, you will not lose access to your medical care or give up any legal rights or benefits.

To help you decide if you would like to participate, we want you to know why we are doing the study, what you will be expected to do, and the possible risks and benefits of being in the study. This form has information to help you make your choice about whether or not to participate.

Purpose of this research:

The purpose of this research study is to better understand how differences in genetic material affect human health.

When you enroll in this study, you will be asked to provide detailed medical history and family health history information. If you had previous genetic testing, you will be asked to provide the data from this testing by asking for this data from the performing lab or allowing a member of our study team to request this data for you. You may be asked to provide a genetic sample. This may include blood or saliva. The study team will use multiple different approaches to find genetic changes which may cause human disease and other traits and better understand genetic changes with unclear meaning. Study staff will contact you and your doctor if they identify something that might explain your medical history. Study duration is expected to last a minimum of 5 years.

Genomic studies, including genome-wide association studies (GWAS), examine genetic differences in the entire human genome (the complete set of human genes) and the association between these genetic differences and health conditions.

As part of this study, we will collect information about your health and your individual genes. This information may be stored scientific data repositories at UCI, at another UC campus, or be sent to a National Institutes of Health (NIH)-designated data repository that includes all kinds of genomic data from studies funded by the NIH. The information may also be maintained by private companies and other institutions.

The aim of collecting this information may be to look for genetic connections that: may increase the likelihood of getting a certain disease (such as asthma, diabetes, heart disease, cancer or mental illness) or a condition (such as high blood pressure or obesity); may affect the progress of a certain disease or condition; or may affect treatments (medicines, etc.) that work for certain diseases in some people, but not in others.

Risks and Benefits:

You may not receive any benefit from participating in this study. One possible benefit is receiving a genetic diagnosis. Your information may also help increase our knowledge of genetic syndromes and eventually lead to more effective diagnoses, management and treatment.

It is possible that the extensive genetic analysis may identify unexpected genetic results that have the potential to pose a present or future risk to your health. This may cause anxiety. Another risk is loss of confidentiality of your study information. Your samples will be assigned a study ID number to help minimize this risk. If a blood sample is obtained, this may cause risks including discomfort and/or bruising; infection, excess bleeding, clotting, or fainting. There may be minimal discomfort in obtaining a saliva sample due to pressure in the mouth from the swab.

Alternatives to participation:

The usual approach for patients who are not in a study is to get advice from their doctor. This advice may include other options for genetic testing.

If you are interested in learning more about this study, please continue reading below. The rest of this form gives you more important information you need to know about the study before you decide if you want to participate. The study doctor or a member of the research team will talk to you about the study and answer all of your questions. We encourage you to discuss this study with your family and anyone else you trust before making your decision. It's important that you have as much information as you need and that all your questions are answered.

Your participation in this research is voluntary.

There will be no penalty or loss of benefits to which you are otherwise entitled if you decide not to be in the study or withdraw from the study later. This means that:

- You do not have to join the study.
- You may change your mind and stop being in the study at any time.
- We will tell you if we make any important changes to the study or if there are any important new findings so that you can decide if you still want to be in the study.

If you are an employee or a medical or graduate student in training at UCI, your decision to participate or not participate will not affect your employment or academic standing.

You are being asked to be in the study because you or your family member have a known or suspected genetic trait. Genetic traits are features or diseases due to variants in genetic material. Genetic material has the instructions in the body on how to grow and develop. There are many genetic traits that do not have a known cause. Some people have genetic testing to try and explain why they have a disease. Some genetic tests do not find an answer. Some genetic tests report an uncertain result. We want to see if newer genetic testing tools can find an answer for people who do not find an answer on standard genetic tests. We also want to identify new genes that cause human disease. We want to also find a better way to determine if an uncertain genetic result causes a disease.

Dr. Eric Vilain is the person responsible for this research study at UCI. He is called the Principal Investigator.

The study team may work with other companies that provide clinical genetic testing for research or commercially.

The National Human Genome Research Institute, part of the National Institutes of Health, is paying for this research to be done.

How many people will be in the study?

This study will involve up to 4,200 people. This will include patients with known or suspected genetic traits and their relatives, such as parents and siblings. We expect half of the participants to be patients and family members recruited at UCI. We expect half of the participants to be patients and family members to be referred from outside of UCI.

What will happen in this research study?

If you decide to participate in the research, you will be asked to provide clinical information and samples for genetic testing. A summary of the study procedures is included below:

- You will be assigned a unique study ID number.
- We will request you provide the study team with detailed medical and family history information. When available, study staff will review your medical records at UCI. Study staff may request you provide copies of additional medical records.
- Study staff will request you provide genetic data from previous genetic testing. The study team will use research computer tools to reanalyze this data.
- Study staff may request you provide a blood sample (up to 2 teaspoons or 10 mL) to collect DNA and RNA and protein. DNA is what stores genetic material in the body. RNA is made using the instruction in DNA. Protein is made using instructions in RNA.
- Study staff may request a cheek swab or a saliva sample to collect genetic material.

Blood draws and cheek swabs will be collected in one of following ways:

- You may schedule a collection at the UCI research unit.
- If you are having clinical blood collection for another reason, an extra sample may be collected for this study.
- Study team may be able to arrange for someone to come to your home to collect a blood sample if needed. This sample collection may be obtained through one of University of California, Irvine's national phlebotomy contacts.
- If you provide a buccal sample, these will be collected either on site or with a kit provided to you with instructions for collection at home and mailing back.
- There are no other required interactions with the study.
- A team of study investigators will review your case history and genetic results. This team will determine what research tests will be performed on your samples and data.
- Your sample may be used for a variety of genetic testing including, but not limited to, Whole Genome Sequencing, Optical Mapping, and RNA sequencing. These are different ways of looking at your genetic material.
- Certain genetic variants may be used in specific studies to test if the variant is likely to cause a genetic trait.
- If the study team requires additional information to better understand a variant found in your testing, the team may contact you to request additional information about your medical history and/or an additional blood or saliva sample.
- After enrollment, you may decline to provide any additional information or samples and still participate in the study.
- If the study team identifies a genetic change that is believed to be medically important, the team will contact you and your doctor to discuss the research result. This may include genetic variants known to cause disease or genetic variants that cannot clearly be classified as "disease-causing" or "benign". A genetic counselor or clinical geneticist on the study team will be able to discuss these results with you. Research results will need to be confirmed in a clinical lab.

How long will my participation in the research study last?

Length of participation:

You may choose to participate in this study for as long as the study is running. The study is expected to last at least 5 years. You may choose to stop participating in the study at any time.

What are the risks and possible discomforts from being in this research study?

The greatest risks of this study are associated with the sample collection, psychologic risks associated with genetic information, and potential for loss of confidentiality of your study information.

- Risks of taking the blood sample are discomfort and/or bruising. Infection, excess bleeding, clotting, or fainting can happen.

- •There may be minimal discomfort in the cheek if a cheek swab sample is obtained.

- You will be assigned a study ID after enrollment on the study. All samples will be analyzed using your study ID. Only the study team will know your personal information so that you can be notified of the results of this study. The team will keep your personal and genetic data on a secure drive. You will be notified immediately if there is a security breach.

- Genetic testing can reveal surprise results that you may not want to know. This includes finding that a parent of a child is not actually the genetic parent. This will not be returned to families unless it is of medical significance.

- Some genetic variations cannot clearly be classified as "disease-causing" or "benign". These are called uncertain results. Some people feel anxiety about uncertain results.

- The genetic testing is looking for new causes of genetic traits. Both new and known genetic diseases may not have known treatments. Some people feel anxiety when there is a diagnosis without a known treatment.

- There may be results related to conditions other than the reason you are being tested. These are called secondary or incidental findings. These include genetic changes related to adult onset conditions such as cancer risks and early onset dementias. There are genetic changes which are called "Medically Actionable." This means that knowing about the genetic change allows doctors to change your treatment plan. This can include avoiding certain medications or more frequent checkups with your doctor. You have the option to decide if you want these results.

- Even without your name or other identifiers, your genetic information is unique to you. There is a potential risk that someone will identify you from your genetic information or learn something about you by looking at your genetic information. This risk may increase in the future as technologies advance and as more researchers study your genetic information. These risks may also affect members of your family. You should discuss your participation in this study with your family and ask the study doctor about any questions or concerns you may have.

There may be risks to your privacy and the privacy of your relatives from storing your information in the repository. Although the data repository have robust procedures in place to protect the confidentiality of the stored information, we do not know how likely it is that your identity could become re-connected with your genetic and health information.

We will do everything we can to protect your information but we cannot absolutely guarantee your privacy or predict how genetic information will be used in the future. People may develop ways in the future that would allow someone to link your genetic or medical information back to you. For example, someone could compare information in a data repository with information from you (or a family member) in another database and be able to identify you (or a relative). It is also possible that there could be violations to the security of the computer systems used to share the codes linking your genetic and medical information to you. There may be other privacy risks that we have not foreseen.

If your genetic information were re-identified, personal information about you, your health, and your risk of disease could become known to others which could potentially have a negative impact or unintended consequences for you and/or your family. A federal law called the Genetic Information Nondiscrimination Act (GINA) will help protect you from genetic discrimination in health insurance and employment. GINA does not protect you against discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. It also does not prohibit discrimination on the basis of already known genetic disease. For more information about GINA go to http://www.genome.gov/10002077.

What are the possible benefits from being in this research study?

There may be no benefit to the participants from this study. A potential benefit of this study is the genetic diagnosis

for a participant. A genetic cause can help direct tests for complications. It can help clarify expectations for disease course. In rare cases, a specific therapy or treatment may exist.

Many people with genetic traits never have a diagnosis. It is not known if research genetic testing approaches will be able to help diagnose people who do not have a diagnosis. This study aims to fill this gap in knowledge. This may help other people in the future.

There is no direct benefit to you from placing your genetic information in the repository. Allowing researchers to study your genetic information may lead to a better understanding of how genes affect health. This may help other people in the future.

What kinds of information will the study collect? Will any information be shared with me?

This study will collect medical information that you provide to understand how your genetic material affects your health. The study team may use your samples to run tests that assess your genetic information such as DNA, RNA, and protein.

Your genes are made up of DNA. DNA is short for deoxyribonucleic acid. DNA contains information that determines in part the traits, such as eye color, height, or disease risk, that are passed on from parent to child.

RNA is made from DNA. RNA is short for ribonucleic acid. RNA is a genetic material that has a major role in making proteins. Proteins are the building blocks of your body, cells, and organs.

Even without your name or other identifiers, your genetic information is unique to you. There is a potential risk that someone will identify you from your genetic information or learn something about you by looking at your genetic information. This risk may increase in the future as technologies advance and as more researchers study your genetic information. These risks may also affect members of your family. You should discuss your participation in this study with your family and ask the study doctor about any questions or concerns you may have.

Most tests done on samples in research studies are only for research and have no clear meaning for health care. If we find that certain data or results from tests done as part of the research have meaning for your health care, we will contact you to let you know what we have found and what this could mean for your health care.

If we think that there are genetic or other research test results that might have meaning for you, these tests should be re-done by a certified clinical laboratory. The study does not have money to do this testing. 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 or other counseling. You or your insurance company will have to pay for those additional services.

The data the study collects about your medical history and genetic information will be assigned a unique study number. Only the members of the clinical study team will have access to the key linking your study number to your name.

Study collaborators will have access to your genetic information and your health information. If you provided a sample through a commercial laboratory, they will also have your name and identifiers. If you use a contracted company for a blood draw through this study, the blood draw company will also have your name and identifiers. If you do not provide a commercial laboratory with your information or use a company to collect your sample, they will not have access to your name or other personal information that directly identifies you.

Other GREGoR research sites may request your genetic information and health information also. They will not have access to your name or other personal information that directly identifies you.

Efforts will be made to limit the use and disclosure of your personal information, including research records, medical records, and Protected Health Information (PHI), to authorized members of the study team and to people who have a need to review this information. Your identifiable personal information will not be given to anyone unless we get your permission in writing, except as described in this consent form or if the law requires it. This information will also only be given for regular hospital care, payment, and hospital management activities. We will make every effort to keep your information private, but no one's privacy can be totally guaranteed.

Your medical record is confidential but, just like any medical record, there are some exceptions under state and federal law.

There are some third parties such as government agencies or other groups within UCI that may check records that identify you without your permission. They might review the study records and your medical records to make sure we

are following the law and protecting the people in the study and to make sure our results are correct. The agencies or groups who might see these records are: the Department of Health and Human Services Office of Human Research Protections, the National Human Genome Research Institute, and the UCI Medical Center Institutional Review Board (the ethics board that reviewed and approved this research study) and the Office for the Protection of Human Subjects.

As part of this study, we will be collecting genetic data about you and will send this data to a National Institutes of Health (NIH)-designated data repository (a repository is a place where data are stored for use in future research). The data will not be labeled with any information that can be used to identify you. This data may be accessed by other researchers around the world.

Your samples and genetic information may be used for research for many years in the future.

Regarding publication of findings:

The results of this research may be presented at meetings or in publications. You will not be personally identified.

If identifiers like your name, address, date of birth, and phone number are removed from the data and samples that are collected during this research, that information or those samples could be used for future research studies or given to another investigator for future research studies without your additional informed consent.

Certificate of Confidentiality:

Sometimes people tell us some very personal information about themselves when they participate in a study and it becomes part of their research record. To help us protect your privacy, the investigators have obtained a Certificate of Confidentiality from the Department of Health and Human Services (DHHS).

- With this Certificate, the investigators cannot be forced (for example, by a court order or subpoena) to give information that may identify you in any federal, state or local civil or criminal court, or in any administrative, legislative, or other proceedings.

- It is important that you know that a Certificate of Confidentiality does not stop you or a member of your family from voluntarily giving information to others about yourself or your taking part in this research. You should also know that if an insurer or employer learns about your participation and you give them permission to receive research information about you, we cannot use the Certificate of Confidentiality to keep your information private from them. This means that you must also actively protect your own privacy.

- Finally, it is important that you know that we are not prevented from taking steps to prevent serious harm to you or to others. If we learn that you or someone else is harming you or others around you, we may be required by law to report this to the police or a social services agency to get emergency help if it is needed.

Genetic Information Nondiscrimination Act (GINA)

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

- Health insurance companies may not request your genetic information that we get from this research.

- Health insurance companies may not use your genetic information when deciding whether to insure you or the amount of money they will charge you.

- Employers may not use your genetic information that we get from this research when deciding to hire, promote, or fire you.

This does not apply to companies with fewer than 15 employees or the United States military.

GINA does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

A Federal law called "HIPAA" provides additional protections of your medical records and related health information. These protections are described below.

What other choices do I have if I don't want to take part in the study?

If you do not want to participate in the study, there are no other choices except not to take part. If you choose not to participate, it will not be held against you.

Will it cost me anything to take part in the study?

There are no costs to you or to your insurance company for taking part in this study. The study will pay for all research genetic testing and collection of samples for the study. If a genetic variant is identified that is clinically important, you or your insurance will have to pay for clinical testing to confirm the variant is present. You or your insurance company will have to pay for the costs of any routine or standard medical care that is not part of the study. This includes standard of care testing that is performed based on genetic diagnoses or variants identified by this study. This may include, but is not limited to, visits to the clinic, having to stay in the hospital, laboratory tests, x-rays, or other tests. If your insurance company does not pay for the routine or standard care, you will be responsible for paying for it.

Will I be paid for taking part in this study?

You will not be paid for taking part in this study.

Your information and samples (both identifiable and de-identified) may be used to help researchers 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 to tell you or to pay you or your family.

What happens if I get hurt or sick because of taking part in this research study?

UCI Medical Center cannot promise that the risks we have told you about or other unknown problems will not happen. If you think that you are hurt, sick, or otherwise harmed because of something to do with the study, please call the Principal Investigator, Eric Vilain, at (949) 824-4090.

- In case of a medical emergency, call 911 or go directly to the hospital. Be sure to tell the Emergency Room personnel and your doctor that you are in this study.

- If you have any non-emergency side effects or bad reactions, call the Principal Investigator, Eric Vilain, at (949) 824-4090.

We will give you any urgent medical care needed because of your participation in this research study if reported in a timely manner. UCI will seek payment from your health insurance company or other third-party payer for any medical care or services you receive. UCI has no program to provide you with any additional payments for any injuries.

HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY

In 1996 the government passed a law known as The Health Insurance Portability and Accountability Act (HIPAA). This privacy law protects your individually identifiable health information (Protected Health Information or PHI). The privacy law requires you to sign an agreement so researchers can use or share your PHI for research purposes. This describes to you how information about you may be used or shared if you are in a research study. It is important that you read this carefully and ask a member of the research team to explain anything you do not understand.

I authorize the Principal Investigator, Eric Vilain MD, PhD, and his research staff to create, access, use, and disclose my PHI for the purposes described below.

This Authorization does not expire.

Protected Health Information that may be used and shared includes:

- Information that identifies you such as name, address, telephone number, date of birth, Social Security number, and other details about you
- Information that relates to your health or medical condition from your medical records
- Information obtained from the study procedures outlined in this consent form, for example: things done to see if you can join the study such as physical exams, blood and urine tests, x-rays and other tests, and any other medical information we learn from you about your health history and family history
- Laboratory results obtained on specimens collected from you (blood, urine, tissue)
- Questionnaires or surveys you complete
- Interviews conducted with you by members of the research team
- Audio/ video recordings
- Photographs

The Researchers may use and share my Protected Health Information with:

The Principal Investigator, other Investigators, Study Coordinators, and all administrative staff in charge of doing work for the study.

Government agencies that have the right to see or review your PHI including, but not limited to:

- The Department of Health and Human Services (DHHS) Office of Human Research Protections (OHRP)
- The Food and Drug Administration
- UCI Institutional Review Board
- Other staff in the Human Research Protections Program at UCI

In addition to the above people and organizations, the Researchers may also use and share my Protected Health Information with:

- Doctors and staff at other places that are participating in the study. The name(s) of the other place(s) that are participating in this study are University of California, Irvine.
- Phlebotomy providers contracted by the study to collect samples.
- Laboratories and other people or organizations that look at your health information in connection with this study.
- The Sponsor of the study and people that the Sponsor may contract with for the study. The name of the Sponsor is National Human Genome Research Institutes, National Institutes of Health
- The Patient Advocate or Research Ombudsman (person who watches out for your best interest)

Also, your primary physician will be contacted if during the course of the study the researcher learns of a medical condition that needs immediate attention.

Should your health information be disclosed to anyone outside of the study, your information may no longer be protected by HIPAA and this Authorization. However, the use of your health information will still be regulated by applicable federal and state laws.

Banking of Tissue Specimens:

We would like to store tissue specimens collected from you in this study in a tissue bank for future research as identified below. The specimens consist of your genetic material including DNA, RNA, or protein, or cells. The tissue bank is maintained by the study team at UCI.

You may change your mind at a later time and request that your sample be destroyed. If you change your mind and want to request that your sample be destroyed, you may do this by contacting our study team in writing.

Please indicate if you approve of your tissue being stored in the tissue bank for future analysis unrelated to this study.

◯ Yes
◯ No

Storage of PHI in a Database
We store personal health information collected from you in this study's database. This is required to notify you about potentially clinically relevant results or to collect additional information. The database is maintained by the study team at UCI.

This information will not be released to anyone outside of our study team without your express written permission except as noted earlier. However, in the future this data may be used to identify other study opportunities you might be eligible for.

Can we have your permission to contact you if we become aware of additional study opportunities?

◯ Yes
◯ No

If you agree to participate in this research study, the research team, the research sponsor (when applicable) and the sponsor's representatives may use Personally Unidentified Study Data. The Personally Unidentified Study Data does not include your name, address, telephone, or social security number. Instead, the researcher assigns a code to the Personally Unidentified Study Data. Personally Unidentified Study Data may include your date of birth, initials, and dates you received medical care. Personally Unidentified Study Data may also include the health information used, created, or collected in the research study. The research team or the research sponsor may share the Personally Unidentified Study Data with others to perform additional research, place it into research databases, share it with researchers in the U.S. or other countries, or use it to improve the design of future studies. They may also publish it in scientific journals, or share it with business partners of the sponsor and to file applications with U.S. or foreign government agencies to get approval for new drugs or health care products.

You do not have to sign this Consent/Authorization.

If you decide not to sign the Authorization, you will not be allowed to participate in the research study.

After signing the Consent/Authorization, you can change your mind and revoke this Authorization.

• If you revoke the Authorization, you must send a written letter to the Principal Investigator to inform him of your decision.

Eric Vilain, MD PhD
University of California, Irvine (UCI)
Department of Pediatrics
1003 Health Sciences Road
Suite 308
Irvine, CA 92617
(949) 824-4090

Additional questions may be sent to Miguel.Almalvez@uci.edu.

• If you revoke this Authorization, researchers may only use and disclose the PHI that was collected for this research study before you revoked the Authorization.
• If you revoke this Authorization, your PHI may still be used and disclosed if you should have an adverse event (unexpected side effect).
• If you change your mind and withdraw the Authorization, you will not be allowed to participate in the study.

You will not be provided the clinical information collected for this research study. Complete genetic data will not be provided to you. You will be notified of genetic variants that the study team believe are medically important. A genetic counselor or clinical geneticist of the study team will be available to discuss these results with you. No clinical report will be generated from the study. If you need a clinical report for your medical care, separate clinical testing to confirm research findings will not be paid for by the study. You or your insurance will need to pay for that testing.

If you have not already received a Notice of Privacy Practices from UCI Medical Center, you may request a copy and will be given one.

Whom can I call if I have questions about this research study?
We want you to ask questions about any part of this research study at any time.

• For questions about the study or the information in this informed consent/parental permission document, call the Principal Investigator, Eric Vilain, MD PhD, at (949) 824-4090 or email the study team at Miguel.Almalvez@uci.edu.

Whom can I call if I have questions or concerns about my rights as a research study participant?

The UCI Human Research Protections and Institutional Review Board department is available to talk with you about:
• Your rights as a research participant
• Your concerns about the research
• A complaint about the research

If you are unable to reach a member of the research team and have general questions, or you have concerns or complaints about the research study, research team, or questions about your rights as a research subject, please contact the UCI's Human Research Protections unit in the Office of Research by calling (949) 824-6068 or (949) 824-2125 Monday - Friday, 8 am - 5 pm; or by e-mail at IRB@research.uci.edu; or by writing us at 160 Aldrich Hall, Irvine, CA 92697.

Incidental Findings

Incidental finds are unintended findings generated by the analysis of genetic data, such as evidence a child's parent is not actually their parent or incest. We do not intend to report incidental findings to you. Even though these are not reported, it may be possible in some situations to infer this information from genetic testing.

Primary Findings

This study will attempt to find genetic changes that are related to your medical history. If we find a genetic change that we believe is related to disease, we plan to tell you about it. Research genetic findings will need to be confirmed in a clinical lab before they can be returned to your medical record. For some of these genetic changes we may not be able to say it definitely is "disease causing" or benign. If you do not want us to communicate any genetic results to you, you have the option below.

I want to be told about genetic results potentially relevant to my medical history.

- ◯ Yes
- ◯ No

Secondary Findings
Sometimes genetic testing finds medically important variants that are not related to the reason for the testing. These are called secondary findings. These may relate to disease risks you may not know about. This includes things like risk for cancer and risk for heart disease. In some cases, secondary findings might change your doctor's treatment plan. These are called medically actionable findings. This may include increased screening tests or specific medicines.

We do not specifically look for secondary findings in this study, but may find these during the course of our analysis.

Would you like to receive secondary findings if we find any (we do not specifically look for these)

- ◯ Yes - but only medically actionable ones
- ◯ Yes - including findings that may not be actionable at this time
- ◯ No

UNIVERSITY OF CALIFORNIA, IRVINE
Experimental Subject's Bill of Rights

The rights listed below are the right of every individual asked to participate in a research study. You have the right:

1. To be told about the nature and purpose of the study.

2. To be told about the procedures to be followed in the research study, and whether any of the drugs, devices, or procedures is different from what would be used in standard practice.

3. To receive a description of any side effects, discomforts, or risks that you can reasonably expect to occur during the study.

4. To be told of any benefits that you may reasonably expect from the participation in the study, if applicable.

5. To receive a description of any alternative procedures, drugs, or devices that might be helpful, and their risks and benefits compared to the proposed procedures, drugs or devices.

6. To be told of what sort of medical treatment, if any, will be available if any complications should arise.

7. To be given a chance to ask any questions concerning the research study both before agreeing to participate and at any time during the course of the study.

8. To refuse to participate in the research study. Participation is voluntary. You may refuse to answer any question or discontinue your involvement at any time without penalty or loss of benefits to which you might otherwise be entitled. Your decision will not affect your right to receive the care you would receive if you were not in the experiment.

9. To receive a copy of the signed and dated written consent form and a copy of this form.

10. To be given the opportunity to freely decide whether or not to consent to the research study without any force, coercion, or undue influence.

If you have any concerns or questions regarding the research study you should contact the research team listed at the top of the consent form.

If you are unable to reach a member of the research team and have general questions, or you have concerns or complaints about the research study, research team, or questions about your rights as a research subject, please contact the UCI's Human Research Protections unit in the Office of Research by calling (949) 824-6068 or (949) 824-2125 Monday - Friday, 8 am - 5 pm; or by e-mail at IRB@research.uci.edu; or by writing us at 160 Aldrich Hall, Irvine, CA 92697.

Are you yourself participating in this study, or are you the Legally Authorized Representative signing for another person?

- ◯ Signing for myself
- ◯ Legally Authorized Representative signing for another
- ◯ Study staff, participant is signing an alternative language consent

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Consent / Parental Permission

- I am the study participant or I am authorized to act on behalf of the participant.
- I have read this consent form or had it read to me.
- I have been invited to take part in a research study. I was told why the research is being done and how long my participation in the study is expected to last. I was told about what will happen in the study and if there are any procedures or drugs that are experimental.
- I was told that taking part in this research is voluntary. I also was told that I can decide not to take part or stop being in it at any time without any penalty to me or any change to the quality of care I receive at UCI.
- I was told about the risks and possible discomforts of taking part in this research study. I was also informed if there are any possible benefits to me if I am in this study.
- I have been given the chance to ask questions about the study, and my questions have been answered. If I have questions later, I can ask one of the people listed in this form.
- I agree to take part in this research study.
- I will receive a signed copy of this Informed Consent/Parental Permission form to keep.

I am legally authorized to act on behalf of the participant. I have read this information and will receive a copy of this form after it is signed.

I agree that we have talked about the risks and benefits of the study, and about other choices. I may decide to stop the subject's participation in this study at any time and it will not affect his/her medical care.

By signing this form, I am confirming the following:
1. The study has been explained to the subject (if the subject is able to communicate, even in a limited capacity);
2. The subject understands the study to best of his or her ability; and
3. The subject (if possible) appears to agree to participate.

First name of participant

_____

Last name of participant

_____

First name of person signing form

_____

Last name of person signing form	_____
Electronic Signature: Please type your first and last name Subject/Parent/Guardian/Legal Authorized Representative	_____
Date/Time	_____