**SITE PRINCIPAL INVESTIGATOR:** Changrui Xiao, MD

**STUDY TITLE:** Clinical and Genetic Evaluation of Patients with Undiagnosed Disorders Through the Undiagnosed Diseases Network

**STUDY SITE:** University of California, Irvine (UCI)

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Cohort: Adult Participant

Consent Version: 10DEC2023

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## WHO DO YOU CONTACT ABOUT THIS STUDY?

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## KEY INFORMATION ABOUT THIS RESEARCH

This consent form describes a research study and is designed to help you decide if you would like to be a part of the research study. This study is taking place at more than one site.

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

- We are asking you to take part in a research study called the Undiagnosed Diseases Network (UDN).
- The UDN is a group of medical and research centers across the United States.
- The goal of this study is to improve diagnosis and care for people with undiagnosed conditions.
- We are asking you to take part because you have an undiagnosed condition.
- Study participation involves an in-person or telehealth visit with the UDN medical center at UCI.
- We will have you see specialists and do tests and procedures to try to find a diagnosis for you.
- Research on your information and specimens that happens after your visit may provide important information for your health. We will contact you if this happens.
- We will share your information and specimens with clinicians and researchers in the UDN.



IRB NUMBER: 15HG0130
IRB EFFECTIVE DATE: 3/18/2024

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

If the individual being asked to participate in this research study is not able to give consent for themselves, you, as the Legally Authorized Representative or parent, will be their decision-maker and you are being asked to give permission for this person to be in this study. For the remainder of this document, the term "you" refers to you as the decision-maker and/or the individual being asked to participate in this research.

## IT IS YOUR CHOICE TO TAKE PART IN THE STUDY

You may choose not to take part in this study for any reason. If you join this study, you may change your mind and stop participating in the study at any time and for any reason. In either case, you will not lose any benefits to which you are otherwise entitled. If you do choose to leave the study, please inform your study team to ensure a safe withdrawal from the research.

## WHY IS THIS STUDY BEING DONE?

The purpose of this research study is to improve diagnosis for people with undiagnosed conditions. We are asking you to join this research study because you have an undiagnosed condition.

## WHAT WILL HAPPEN DURING THE STUDY?

### Visit with the UDN medical center

You will likely travel to UCI, one of the UDN medical centers, to be seen by medical providers. In person visits can vary in length and will be discussed with you during the planning process. You may also have visits conducted by telehealth.

We will collect information from your prior medical records to learn as much as we can about you and your prior evaluations. We may also collect information from your future medical records for as long as you are enrolled in this study.

### Clinical tests and procedures

During the visit we may:

- Ask you questions about your health and the health of your family members.
- Do a physical exam.
- Collect specimens, like blood, urine and/or spinal fluid, for clinical and genetic testing and other medical studies as clinically indicated.
- Do muscle, nerve, gastrointestinal or other tissue biopsies as clinically indicated.

- Do imaging studies, such as X-rays, MRI (magnetic resonance imaging), or CT (computerized tomography) scans, ultrasounds, elastography as clinically indicated.
- Take photographs or videos of you.

- Recommend other clinical tests and procedures during the visit to help find a diagnosis.

We will explain all the clinical tests and procedures to you and ask your permission before they are done.

**Genetic testing**

Genetic tests look at your genetic information for changes that may explain your condition.

Genetic testing can provide three types of results:
1. Positive (pathogenic): One or more changes were found that are very likely to cause or contribute to a condition. Such changes may be causing you to have signs and symptoms of your undiagnosed condition, may cause you to have signs and symptoms of a condition in the future, or may be important to the health of your children.
2. Negative (non-diagnostic): No changes were found that are currently known to cause or contribute to your undiagnosed condition.
3. Inconclusive (variant of uncertain clinical significance, VUS): One or more changes were found, but there is not enough information available to determine the meaning of the change. Additional testing may be needed if a VUS is found, and it is possible that we will never be able to figure out if a VUS is causative or not.

*Primary findings:*
We may discover genetic results that are related to some or all of your symptoms. These types of results are called “primary findings”.

If we discover a primary finding, we will give you this result during a genetic counseling session with your UDN clinical team. It will also be listed on your genetic testing report, which will be part of your medical record. If other family members had genetic testing as part of this study, your report will include information about whether these family members have or do not have the primary finding. On the report, their relationship to you (but not their names) will be listed. Therefore, you may learn something about the genetic results of your family members when we explain your results to you.

*Other findings:*
We could also discover genetic results that are not related to your symptoms. Some of these results may be related to conditions with treatment or management options. These types of results are called “medically actionable findings”. We could also discover results that are related to the chances of having a child with a certain medical condition. These types of results are called “carrier status findings”. Medically actionable and carrier status findings may provide information that is not expected. You have the option to receive medically actionable and carrier status findings. Please indicate your choices by initialing below.

_____ I would like to receive my medically actionable findings discovered during this study.

_____ I would like to receive my carrier status findings discovered during this study.

_____ I would NOT like to receive medically actionable or carrier status findings discovered during this study.

Research into your condition using genetic testing may take years. At first, we may not find a genetic change that explains your condition. However, over time we may discover a genetic cause for your symptoms. If we learn new information we believe is important to your health, we will try to re-contact you to find out your interest in learning new information about your genetic results or having more tests done.

*Limitations of genetic testing:*
There are several limitations of genetic testing.

First, this genetic test cannot find all genetic changes that cause disease. A person may have a genetic change that causes a disease; however, this genetic test may be unable to detect the change. Therefore, a test report with no findings does not mean that the person is not at risk for any genetic conditions.

Second, this genetic test does not replace other types of clinical testing. If you or your UDN clinical team are concerned about a specific genetic condition, then further testing may be indicated.

It is possible to request a copy of your genetic data for additional analysis or to share with another research group. This should be discussed with your UDN clinical team.

**Authorization to disclose/release genetic information:** You have the option to name a person to receive your genetic testing results from this study, in case you lose decision-making capacity or pass away before receiving them. Your genetic results may be important for your family members to learn as you may share similar genetic information.

_____ I authorize the disclosure of my genetic results to the named person below in the event that I should lose decision-making capacity or pass away before receiving all genetic results myself. I understand that once the results I have authorized to be disclosed reach the noted recipient, that person may re-disclose them, at which time they may no longer be protected under privacy laws.

*Recipient Authorized to Receive Genetic Information:*

Recipient's Printed Name:
_____
Relationship to Participant:
_____
Date of Birth:

Address:

Telephone:

Email:

**Research tests and procedures**

During the visit we may ask to:
- Draw blood specimens (usually about 1-8 teaspoons).
- Collect a urine specimen.
- Have you fill out surveys or answer interview questions.
- Do a skin biopsy (removal of a small piece of skin about half as big around as a pencil eraser). The skin cells can be grown and tested for evidence that a gene or gene product is not working correctly.

You have the option to undergo a skin biopsy. Please let us know if you agree to have a skin biopsy by initialing below.

_____ Yes _____ No
Initials Initials

In some cases, we may use cells (from skin, blood, or other tissues) to make "induced pluripotent stem cells." Induced pluripotent stem cells can form any type of cell in the body. The creation of induced pluripotent stem cells is sometimes necessary because it is difficult to get the special cells that are not working correctly in undiagnosed conditions.

We may recommend other research tests and procedures to help find a diagnosis. We will explain all the research tests and procedures to you and ask your permission before they are done.

You will be told whether a test or procedure is research or clinical.

**Sharing results from the evaluation**

We will meet with you at the end of the visit to talk to you about the clinical and research tests and procedures that were done and any results that are available. We will give you the contact information for the UDN clinical team in case you have questions after the visit.

There will not be formal results returned from these research tests and procedures; however, if we learn anything important related to your health or diagnosis through these research tests and procedures, we will try to contact you.

**HOW LONG WILL THE STUDY TAKE?**

Your visit may last 1-5 days. Each day will range from 1-8 hours in length. If you have a telehealth visit that may last several hours.

After your visit, we will share with your referring medical provider what tests and procedures were performed and any clinical results that we found. Most people will not come back to the UDN medical center after their visit.

Research on your information or specimens usually continues after the visit and may provide important information for your health. We will try to contact you if this happens. If you wish to be contacted, you must let the UDN know about changes in your address or phone number.

We may also contact you in the future for interviews and surveys.

**HOW MANY PEOPLE WILL PARTICIPATE IN THIS STUDY?**

We plan to have approximately 2,000 people participate in this study at UCI. Up to 20,000 people might also participate at other study sites.

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

Risks you could experience during this study include:

Skin biopsy. The risks of a skin biopsy include a reaction to the anesthetic, the possibility of bleeding, and the possibility of infection. A very small scar always occurs at the biopsy site. It is possible that a suture may be needed to close the area where the skin was removed.

Blood collection. There may be some discomfort when we collect your blood with a needle. There is a small chance that you may develop a bruise, feel lightheaded, faint, or develop an infection at the needle site. The amount of blood drawn will conform to the guidelines at the UDN medical center where you are seen.

Photographs and videos. Photographs and/or video recordings of the face and body may be embarrassing to some participants. There is a risk of loss or theft of the photographs and/or videos that may cause the participants to be identified by people not connected with the study.

Genetic testing.

- Learning you have a genetic change that causes or contributes to a condition could lead to emotional or psychological harm.
- Research about genetic causes may reveal information that is not only about one person, but also about their relatives. It is possible that your relatives would be upset to learn that they may be at risk for a condition because of your participation in this research study.
- Issues of adoption and parentage (biological parenthood as well as degree of relatedness) may be discovered in this study. If genetic testing shows that a family relationship is different than previously thought, it is our policy not to tell you this information unless it affects the physical health of you or your family. However, in the discussion of test results it may be possible to infer that this had likely occurred. It is also possible to determine from this study if parents are closely related. If this finding should occur and the parent is an unmarried minor (under

the age of 18 years) and not otherwise emancipated, this information may need to be reported to the appropriate authorities in certain states.
- We may publish results of this research study, including information about your family and other medical information. While we make efforts to de-identify such information, it is possible that you and/or a family member could be recognized because of such publications.
- Some genetic information can help predict future health problems of you and your family and this information might be of interest to your employers or insurers. The Genetic Information Nondiscrimination Act (GINA) is a federal law that prohibits plans and health insurers from requesting genetic information or using genetic information. It also prohibits employment discrimination based on your health information. However, GINA does not address discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. GINA also does not protect you against discrimination based on an already-diagnosed condition or disease that has a genetic component.

Unanticipated medical information. During this study, it is possible that we will find information about your health that you did not expect. We will give the information to you or your medical provider if this occurs. Your UDN clinical team will be available to explain the information to you or to provide you with a referral as needed.

Use of information. There is a potential risk of loss of privacy and confidentiality. Every effort will be made to protect your privacy and confidential information, but this cannot be guaranteed. Some people are concerned that information about them from their medical records could be released.

## WHAT ARE THE BENEFITS OF BEING IN THE STUDY?

You might not benefit from being in this study. You will receive medical care and genetic counseling during this study, which may be beneficial, but this can also be received outside of this study. There is a possibility that you will receive a diagnosis to explain your condition.

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

In the future, other people might benefit from this study because of your participation. Research on your specimens may help us better understand your condition and similar disorders.

## WHAT OTHER OPTIONS ARE THERE FOR YOU?

You can choose to see other medical providers. You can discuss other options for diagnosis or treatment with your medical providers.

## EARLY WITHDRAWAL FROM THE STUDY

You may stop participating in this study at any time. If you choose, you may ask to have your clinical and research information and specimens destroyed, with the exception of clinical information in the official medical record, information put into controlled access databases, information and specimens shared outside of the UDN, and cell lines generated. If you withdraw

from the study, no new information about you will be collected for study purposes unless the information concerns an adverse event (a bad effect) related to the study. If such an adverse event occurs, we may need to review your entire medical record.

Your decision not to participate or to withdraw from the study will not involve any penalty or loss of benefits to which you are entitled and will not affect your access to health care. If you do decide to withdraw, we ask that you contact your UDN study team in writing and let them know that you are withdrawing from the study. Their contact information is on the first page of this form.

During the study, if you do not comply with study procedures or do not follow instructions given by UDN medical providers, researchers, and staff, your involvement in the protocol may be terminated.

## STORAGE, SHARING AND FUTURE RESEARCH USING YOUR SPECIMENS AND DATA

### Sharing specimens and information within the UDN

We will share your clinical and research information and specimens in the UDN and the information and specimens will be connected to your name and date of birth. Your clinical and research information will be stored indefinitely at the Coordinating Center and your UDN medical center. Clinical information from this study that relates to your general medical care will be included in your medical record.

### Sharing specimens and information outside of the UDN

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

### Papers

It is possible that some information from this study will be published in medical papers. However, your name or date of birth will not be included in these papers. If a photograph of you is published, you may be identifiable. You may be asked to sign a separate consent form for this purpose. We may publish a chart (pedigree) that uses symbols to show your family and who is affected with the condition, but we will not use your family's name. If you have a unique family, others may still be able to recognize the family.

### Education

Your medical and genetic information may be used for teaching healthcare professionals about rare conditions. If a photograph of you is used, you may be identifiable.

**Will your genomic data be shared outside of this study?**

As part of this research study, we will put your genomic data in a large database for broad sharing with the research community. These databases are commonly called data repositories. The information in this database will include but is not limited to genetic information, race and ethnicity, and sex. If your individual data are placed in one of these repositories, they will be labeled with a code and not with your name or other information that could be used to easily identify you, and only qualified researchers will be able to access them. These researchers must receive prior approval from individuals or committees with authority to determine whether these researchers can access the data.

Summary information about all of the participants included in this study (including you) is being placed in a database and will be available through open access. That means that researchers and non-researchers will be able to access summary information about all the participants included in the study, or summary information combined from multiple studies, without applying for permission. The risk of anyone identifying you with this information is very low.

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

Your individual genomic data and health information will be put in a controlled-access data repository. This means that only researchers who apply for and get permission to use the information for a specific research project will be able to access the information. Your genomic data and health information will not be labeled with your name or other information that could be used to identify you. Researchers approved to access information in the repository must agree not to attempt to identify you.

In the event of an unexpected breach of confidentiality, a federal law called the Genetic Information Non-Discrimination Act (GINA) will help protect you from health insurance or employment discrimination based on genetic information obtained about you. In California, state law (CalGINA) requires that employers with 5 or more employees may not use your genetic information, obtained from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment. However, these laws do not protect you against discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

If you would like more information about the federal GINA law go to: http://www.genome.gov/Pages/PolicyEthics/GeneticDiscrimination/GINAInfoDoc.pdf or CalGINA: http://www.leginfo.ca.gov/pub/11-12/bill/sen/sb_0551-0600/sb_559_bill_20110906_chaptered.pdf

**How long will your specimens and data be stored by theUCI?**

Your specimens and data may be stored by the UCI indefinitely.

**Risks of storage and sharing of specimens and data**

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

At your request, we may be able to share your medical and research data and specimens from this study with medical providers, researchers, and commercial entities outside of the UDN. Once such data or specimens are shared, we will not have control over how they are used.

This consent form refers to your participation in the UDN. In the future, it is possible that we may ask you to participate in other studies that would require more specimens or testing. Even if you sign this consent form, you do not have to participate in these other research studies. If you are asked to participate in other research studies, you will be given additional consent forms. You are free to withdraw from any or all research studies at any time without penalty or loss of any benefit to which you are otherwise entitled.

**PAYMENT**

**Will you receive any type of payment for taking part in this study?**

You will not receive any payment for taking part in this study. It is possible that research using your specimens and information may help researchers to develop medical tests or treatments that have commercial value. However, there is no plan to compensate you from future commercial developments and/or patents.

**COSTS**

**Will taking part in this research study cost you anything?**

No. Taking part of this research study will not cost you anything. During this study, you will not be charged for research tests and procedures.

The costs of your clinical tests and procedures may be covered through health insurance. When we bill your insurance company, you will be responsible for meeting your deductible and co-payments that are required by your insurance policy.

If you do not have insurance or do not want your insurance to be billed, you may be responsible for the cost of clinical tests and procedures. Patients who have been screened and approved as part of the institution's financial assistance policy may be eligible to have the cost of clinical tests and procedures waived or discounted. The study team can provide more information about this process.

We will work with local and national partners to assist in supporting transportation and housing expenses for your UDN visit for you and one family member or caregiver. However, we may not be able to support your travel expenses.

You may be able to receive some reimbursement for out-of-pocket insurance and travel costs through outside organizations. The study team can provide contact information for these organizations, like the National Organization for Rare Disorders (NORD), if needed.

## CLINICAL TRIAL REGISTRATION AND RESULTS REPORTING

A description of this study will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

## CONFIDENTIALITY PROTECTIONS PROVIDED IN THIS STUDY

The research team, authorized UCI personnel, and regulatory entities such as the Food and Drug Administration (FDA) and the Office of Human Research Protections (OHRP), may have access to your study records to protect your safety and welfare.

While the research team will make every effort to keep your personal information confidential, it is possible that an unauthorized person might see it. We cannot guarantee total privacy.

### Future Research Use

Researchers will use your specimens and information to conduct this study. Once the study is done using your specimens and information, we may share them with other researchers so they can use them for other studies in the future. We will not share your name or any other private identifiable information that would let the researchers know who you are. We will not ask you for additional permission to share this de-identified information.

### Will your medical information be kept private?

We will share your medical information and specimens in the UDN and the information and specimens will be connected to your name. Information from this study that relates to your general medical care will be included in your medical record at the UDN medical center.

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

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

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

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

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

**Certificate of Confidentiality**

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

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

The Certificate does not protect your information when it:

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

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

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

**WHAT HAPPENS IF YOU ARE INJURED BECAUSE YOU TOOK PART IN THIS STUDY?**

It is important that you promptly tell the researchers if you believe that you have been injured because of taking part in this study. You can tell the researcher in person or call them at the number listed at the top of this form.

If you are injured as a result of being in this study, UCI will provide necessary medical treatment. The costs of the treatment may be covered by the University of California or billed to you or your insurer just like other medical costs, depending on a number of factors.

The University and the study sponsor do not normally provide any other form of compensation for injury. For more information about this, you may call UCI Human Research Protections (949) 824-8170 or by e-mail at IRB@research.uci.edu.

**PROBLEMS OR QUESTIONS**

If you have any problems or questions about this study, or about your rights as a research participant, or about any research-related injury, contact the site Principal Investigator, Dr. Changrui Xiao, Telephone: 714.456.7002, Email: changrx@hs.uci.edu. Other researchers you may call are: Andria Meyer, Telephone: 714.456.2309, Email: apontell@hs.uci.edu. For questions about your rights while in this study, call the NIH Institutional Review Board at (301) 435-8712.

**CONSENT DOCUMENT**

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

## HOW DO I AGREE TO PARTICIPATE IN THIS STUDY?

You should not sign and date this consent form until all of your questions about this study have been answered by a member of the research team listed at the top of this form. You will be given a copy of this signed and dated consent form, and the attached "Experimental Subject's Bill of Rights" to keep. **Participation in this study 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 future relationship with UCI or your quality of care at the UCI Medical Center.

If, during the course of this study, significant new information becomes available that may relate to your willingness to continue to participate, this information will be provided to you by the research team listed at the top of the form.

Your signature below indicates you have read the information in this consent form and have had a chance to ask any questions you have about this study.

**Note: If the research described in this form involves your protected health information (PHI), you will be asked to sign separate UC HIPAA Research Authorization form for the use of your PHI.**

***I agree to participate in the study.***

| | |
|---|---|
| _____ | _____ |
| **Subject Signature** | **Date** |
| _____ | |
| **Printed Name of Subject** | |
| _____ | _____ |
| **Signature of Person Obtaining Informed Consent** | **Date** |
| _____ | |
| **Printed Name of Person Obtaining Informed Consent** | |

***A witness signature is required on this consent form <u>only</u> if: (Researchers: check which one applies)***

**IMPORTANT! If no witness signature is required, this witness signature section of the consent form may be left blank.**

☐Consent is obtained from the subject via the Short Form process, as approved by the IRB.
☐The subject has decision-making capacity, but cannot read, write, talk or is blind.
☐The subject's guardian/legally authorized representative (LAR) cannot read, write, talk or is blind.
☐The IRB specifically mandated a witness signature for this study (e.g., high risk and/or invasive
research procedures).

**For the witness:**
I confirm that the information in this consent form was accurately explained to and understood by the subject or legally authorized representative and that informed consent was given freely.

_____ _____
**Witness Signature** **Date**
Note: The witness must be impartial (i.e. not a member of the subject's family, not a member of the study team).

_____
**Printed Name of Witness**

**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 are 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.

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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) 824-8170 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 92697-7600.