UNIVERSITY OF CALIFORNIA, IRVINE
RESEARCH SUBJECT INFORMATION AND CONSENT FORM

PARTICIPANT NAME: _____

TITLE: EVOLVE-MI: A Pragmatic Randomized Multicenter Trial of EVOLocumab Administered Very Early to Reduce the Risk of Cardiovascular Events in Patients Hospitalized With Acute Myocardial Infarction

PROTOCOL NO.: AMG 20190184
WCG IRB Protocol #20222099
UCI IRB #2913

SPONSOR: Amgen, Inc.

INVESTIGATOR: Ailin Barseghian El-Farra, MD
101 The City Drive South
Orange, CA 92868
USA

SUB-INVESTIGATOR: Nathan Wong, PhD
Andy Lee, MD
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Antonio Frangieh, MD

STUDY-RELATED PHONE NUMBER(S): (714) 456-6699 (24 hours)

Version 3.00 15 Mar 2023

You are being asked to participate in a research study. Participation is completely voluntary. Please read the information below and ask questions about anything that you do not understand. A researcher listed below will be available to answer your questions.

In this consent form, "you" always means the study subject. If you are a legally authorized representative, please remember that "you" means the study subject.

You are being invited to participate in a research study. This form gives you important information about this study to help you decide if you want to take part in it.

Please take the time to read this information carefully. The study team will explain the details of this study to you and you can ask questions. You can also discuss this study with other people such as your legally authorized representative, your caregiver (hired aid, family, friend) or regular doctor.

You can choose whether to take part in this study or not take part. Your participation in the study is voluntary. If you do not want to participate, your regular care will not be affected and will not result in any penalty or loss of benefits to which you are otherwise entitled. If you do choose to participate in this study it will not alter your regular care including emergency care, if required.

If you choose to join this study now, you may change your mind and stop participating at any time, without giving a reason and without penalty or loss of benefits to which you are otherwise entitled.

If any new information related to this study becomes available and may impact your willingness to continue participation in the research study, the study team will notify you or your legally authorized representative in a timely manner and advise you of options at that time including continuing in the study or stopping.

If you decide to take part in this study, you will be asked to sign and date this form. You will receive a copy of the signed form. If you are currently taking part in another research study, you may not be able to join this study. If you are involved in another study, you should mention this to the study doctor who has asked you for consent and discuss whether or not it involves an unapproved drug or device.

You may be asked to provide consent in person or virtually (e.g. through a link to an electronic form by text message, email, or similar mechanism). If anything changes in this document throughout the course of this study you may be asked to provide your consent again. At the time of reconsent, the study team will explain the updates to you and you may ask any questions.

Contact Information:

Principal Investigator (study doctor): Ailin Barseghian El-Farra, MD
UCI Health
101 The City Drive South, Orange, CA 92868
barsegha@hs.uci.edu

Sponsor: Amgen Inc. Referred to as “Amgen” throughout this form.

Amgen Medical Information/Global Patient Safety

PHONE: +1-800-772-6436 (+1-800-77-Amgen)

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time. Information on this study (2021-005272-19) and its results will also be posted in a similar format on the European website at www.clinicaltrialsregister.eu or on the European Union (EU) Clinical Trials Information System (CTIS).

A plain language summary of the results from this study will be available for you to view after the study has been finished. You will receive information from the study team on where you can find this summary on the internet once you complete the study.

1. WHAT YOU SHOULD KNOW ABOUT THIS STUDY

a. Why is this study being done?

You are being asked to take part in this investigational study because you have been hospitalized for a heart attack. This study is being done to learn whether regular healthcare, combined with early treatment with a cholesterol lowering drug called evolocumab (Repatha®) reduces heart attack, stroke, procedures to improve blood flow, and death, compared to regular healthcare alone.

b. How many people will take part in this study?

Approximately 4,000 people are expected to take part in this study.

c. Will you be enrolled in the study if you meet the eligibility criteria?

You must meet the conditions the study is looking for in order to be enrolled. Even if you meet the conditions you might not be enrolled for another reason, for example, if the study is full or has been stopped for any reason. If you do not meet study conditions you will not be able to join the study. The study doctor will discuss other options with you and/or refer you to your regular doctor.

d. How long will you be participating in this study?

If you meet the conditions of the study and are enrolled, you may be in this study for 3.5 years or longer, depending on when you joined the study. If required for further safety follow up, additional information may be collected from your medical records after you finish.

e. What study drug is being tested?

Evolocumab is made by Amgen Inc., a for-profit biopharmaceutical company. It is approved by health agencies throughout the world including the U.S. Food and Drug Administration (FDA), the European Medicines Agency (EMA), and the Brazilian Health Regulatory Agency (ANVISA) to lower cholesterol and reduce the risk of heart attack and stroke. Evolocumab, has been approved in all countries where the study is being conducted; however, its use in this study is considered investigational.

f. What are the chances you will receive the study drug?

By signing this document, you agree to be screened for this study and if you are eligible, you will be assigned to 1 of 2 groups:

1 – to receive the study drug in addition to cholesterol lowering drugs per standard of care or

2 – to receive cholesterol lowering drugs per standard of care alone without additional study medicine.

Randomization: You will be assigned to a study group by chance (like a coin flip) rather than by a medical decision made by the researchers. The treatment you receive may prove to be less

effective or to have more side effects than the other study group(s), or than standard treatments available for your condition.

g. What will be asked of you if you take part in this study?

If you agree to take part in this research study, you or your legally authorized representative will be asked to first read, sign and date this informed consent form. Then, to find out if joining the study is right for you, the following information will be collected from you or your medical record: age, sex, race, ethnicity, medical history, current medications, height, weight, blood pressure, LDL-C, and pregnancy test (for women capable of conceiving children).

Once you have been assigned to a study treatment group, there are no required clinic visits.

For the group assigned to receive study drug

If you are assigned to the group receiving study drug, your first supply of study drug will be provided after you are randomized into the study. The study medicine is pre-filled in a device that looks like a pen, called an autoinjector/pen. You will be taught how to use the prefilled autoinjector/pen to inject the study drug under your skin every two weeks, and how to dispose of the device. Your study team will teach you how to use and store your drug at home. Please reference the Instructions for Use insert within the study drug package for information on storage and how to inject.

Resupply of evolocumab will be done primarily through participant pick up from a local pharmacy. In the case that you are unable to pick up drug from a local pharmacy, your study doctor will discuss possible resupply options through other mechanisms with you (e.g. you may be asked to pick up from your study site or it may be delivered to you).

For both groups

Whether you are in the study drug group or regular healthcare group, it is important that you continue with your regular healthcare including continuing to follow the advice of your regular doctor.

Approximately every 12 weeks during the study, the following information will be collected from your medical record or by the study team contacting you by text, email or phone to ask about:

- current medications
- any unexpected medical problems that are serious or led to stopping study drug
- healthcare you may have received at other hospitals, clinics, or urgent/emergency care centers
- results of blood or urine tests ordered by your regular doctor
- possible heart attack, stroke or procedures to improve blood flow and to make sure you’re still alive

You will also have the opportunity to ask any questions you may have. If the study team cannot reach you or get the information that they need from your medical records, they might collect information from your relatives, other providers or public sources of information. The study team may use a qualified third-party vendor to help get this information.

h. Study Assessments and Procedures:

Women capable of conceiving children must have a negative pregnancy test within 10 days before joining the study.

i. Are there any risks from taking part in this study?

There may be risks related to taking part in this study from the study drug, the autoinjector/pen or from blood sample collection.

Also, your condition may get better but it could stay the same or even get worse. The risks of the study drug are described in Section 3 below.

If you take part in this study, you or your caregiver should tell the study team immediately if you have any unusual health problems, injuries, side effects, or complaints about the study drug or autoinjector/pen, even if you do not think these issues are caused by the study, the study drug, or the autoinjector/pen.

j. Are there any benefits of taking part in this study?

The study drug has been shown to reduce the risk of heart attack and stroke. This study may help the sponsor understand whether starting the study drug soon after a heart attack is beneficial. There is no way to know if taking part in this study will help you. The information from this study might help future heart attack patients.

k. Do you have any other treatment choices?

You can choose not to take part in this study. Your doctor will treat your cholesterol according to local guidelines regardless of whether or not you participate. If you do not wish to take part, the study doctor will discuss the benefits and risks of other treatments with you. Make sure you understand all of your choices before you decide to participate in this study. You may leave the study or sub-study at any time and still have these other treatments available to you.

2. FURTHER INFORMATION ON YOUR RIGHTS ON STUDY TERMINATION

a. Can you stop taking part in the study?

You can stop participating in the study at any time for any reason. The study doctor or Amgen may also stop you from taking part in this study at any time if the study doctor thinks that being in the study may cause you harm, or for any other reason. The study doctor will tell you if this happens. Also, Amgen may stop the study at any time.

When you stop participating in this study, all information collected from you before you stopped taking part in the study may still be used by Amgen and its authorized representatives.

If you want to stop taking part in the study, the study doctor will discuss the following with you:

- You can stop taking the study drug but continue with some or all other study activities

- You can completely leave the study and have no more contact with the study team. Even if you decide to completely leave the study, public records and/or public sources of information, and/or a qualified third-party vendor, may still be used to collect health related information about you until the study ends to the extent permitted by law.

If you stop taking part in the study or the study ends early, you will stop receiving the study drug.

3. DETAILED SAFETY INFORMATION – POTENTIAL RISKS AND DISCOMFORTS

a. What are the likely risks with evolocumab?

Evolocumab may cause all, some, or none of the side effects listed below. These side effects can be mild but could also be serious, life-threatening, or even result in death. The study may include risks that are unknown at this time. As of January 2022, approximately 33,565 people have received evolocumab in research studies. As of March 2022, since it was first approved for sale in July 2015, approximately 1,544,523 people have been prescribed evolocumab for treatment.

Side effects that other people have had and that are thought to have been caused by evolocumab are:

Common side effects: Common cold, back pain, nausea, flu (influenza), joint or muscle pain, injection site reactions (pain, redness, bruising, swelling, or bleeding), rash, headache

Uncommon side effects: Hives, flu-like symptoms (high temperature, sore throat, runny nose, cough and chills)

Rare side effects: Swelling of face, mouth, tongue, or throat.

Potential side effects with evolocumab: Rare allergic reactions to evolocumab have been reported, including rash, hives and swelling of face, mouth, tongue, or throat. In addition, you may experience other symptoms of an allergic reaction including headache, itching, flushing, swelling, shortness of breath, nausea (queasy/feeling like you need to throw up) and sometimes vomiting. Severe allergic reactions can cause dizziness, severe skin reactions, difficulty breathing or swallowing, a decrease in blood pressure, and could be life threatening or even result in death.

You may also experience other potential side effects with evolocumab that have never been seen before, including very low levels of cholesterol and antibody formation (your body may make proteins that may stop evolocumab from working or may cause side effects). In clinical studies with evolocumab to date, no patients have made antibodies that caused evolocumab not to work or that caused side effects.

b. What are the risks of using evolocumab in combination with other drugs?

Tell the study doctor or the study staff about any drugs you are taking, have recently taken or are planning to take, including herbal remedies, supplements, experimental therapies and drugs you take without a prescription. The side effects of using evolocumab in combination with other drugs are unknown at this time. Please discuss any concerns you may have with the study doctor.

c. What are the risks associated with procedures done in this study?

The known risks and side effects of study related tests or procedures are noted here.

Blood Draws: Possible side effects of having blood drawn are tenderness, pain, bruising, bleeding, and/or infection where the needle goes into the skin and vein. Having your blood drawn may also cause you to feel nauseated and/or lightheaded.

d. What are the risks associated with the prefilled autoinjector/pen used to give evolocumab during this study?

If you are assigned to the study drug group, the study drug will be provided in a prefilled autoinjector/pen to inject evolocumab under your skin.

When using the prefilled autoinjector/pen you may experience all, some, or none of the following: pain, bruising, bleeding, and/or infection at the injection site.

You may experience an allergic reaction to the needle cover in the autoinjector/pen which contains dry natural rubber, made from latex. Tell your study doctor or the study team if you are allergic to latex.

It is possible that the prefilled autoinjector/pen will not work properly during the injection. If this occurs, it is possible that you could receive an incomplete dose or even no dose at all of evolocumab. Contact your study doctor immediately if you believe that your prefilled autoinjector/pen used to administer evolocumab did not work properly during the injection.

e. What are the risks associated with being pregnant and/or breastfeeding and participating in this study?

It is not known if the study drug is harmful to an unborn or breastfed baby. If you or your partner become pregnant during this study, potential risks could include the loss of the pregnancy (a miscarriage) or birth defects. Pregnant or breastfeeding women, and women planning to become pregnant, should not participate in this study. If you are assigned to take the study drug and become pregnant or breastfeed during this study, you should discontinue use of the study drug. If you become pregnant, breastfeed, or father a child during this study tell the study team immediately as further information may be asked of you (the study doctor will discuss the details with you).

Birth Control Information

Female Participants

If you are a woman who can become pregnant, you must have a negative pregnancy test before joining the study and must be willing to abstain from sex or use an effective method of birth control for the entire time you are enrolled in the study and for an additional fifteen (15) weeks after the last dose of study treatment. You must discuss your pregnancy prevention method with the study doctor to ensure it is acceptable.

Male Participants

Male participants are not required to use birth control during treatment with evolocumab. However, you should let your female partner know you are in this study.

4. PAYMENTS AND COSTS

a. Will I be paid for being in the study?

You will be paid up to a total of $260 according to the following schedule:

$20 after completion of week 12 follow-up
$80 after completion of year 1 follow-up
$80 after completion of year 2 follow-up
$80 after completion of year 3 follow-up

If you leave the study early, or if we have to take you out of the study, you will be paid only for the follow-up you have completed. It is important to know that payments for participation in a study may be taxable income.

b. Will I have to pay for anything?

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

You and /or your health plan/insurance will be billed for the costs of any standard medical care you receive to diagnose and/or treat any medical condition(s) outside of this study. You will also be responsible for any deductibles or co-payments that would normally be associated with these standard medical costs.

5. CONFIDENTIALITY

Information from this study will be given to the sponsor. "Sponsor" includes any persons or companies which are contracted by the sponsor to have access to the research information during and after the study.

The information will also be given to the U.S. Food and Drug Administration (FDA). It may be given to governmental agencies in other countries where the study drug may be considered for approval.

Medical records which identify you and the consent form signed by you will be looked at and/or copied for research or regulatory purposes by:

- the research team
- authorized UCI personnel
- the sponsor

and may be looked at and/or copied for research or regulatory purposes by:

- the FDA
- Department of Health and Human Services (DHHS) agencies;
- governmental agencies in other countries;

- the University of California; and the Western Copernicus Group (WCG) IRB, Inc.

Absolute confidentiality cannot be guaranteed because of the need to give information to these parties. If the results of this study are made public at meetings or in scientific journal articles, information that identifies you will not be used.

Medical Care
If you agree to participate in this research study, a signed copy of this consent document and the privacy authorization form may be filed in your electronic medical record (EMR) and your study participation may be added to your EMR. This information will be used for your care and treatment and for healthcare operations, which may include billing and payment.

Federal and state privacy laws give patients the right to access information about their care and treatment contained in their medical record. During this study, you may not be able to access certain information related to this study in your EMR until the study is complete to ensure that the study remains unbiased. By consenting to participate in this study, you are also consenting to this possible temporary withholding of your records. If necessary for your care, this information will be provided to you or your physician.

a. Who will see my research information?

Data is being collected for the scientific purposes of this research study, as described in this document.

You do not have to give us permission to use your personal and protected health information (PHI). If you do not agree, then you may not join this study, however this will not affect any non-study treatment you may receive.

We will see, use and disclose your information only as described in this form or other privacy notices provided to you; however, there is a potential that your information may be re-disclosed by a person or entity associated with this study and would no longer be protected.

Your personal information will not be made available publicly. If results of the study are published, your personal information will remain confidential. We will do everything we can to maintain the confidentiality of your personal information, but confidentiality cannot be guaranteed. During this study, information that can be used to identify you, such as your name, address, etc., will be de-identified, and you will be referred to by a number.

Information about you that will be seen, collected, used and disclosed in this study, as allowed by regulations:

- Name and demographic information (age, sex, race, ethnicity, address, phone number, etc.)
- Portions of your previous and current medical records that are relevant to this study, including but not limited to diagnosis(es), history and physical, laboratory or tissue studies, radiology studies, procedure results
- Study visit and study test records
- Blood samples and the data associated with the samples

The data collected for this study may be sent to other countries to be studied, for submission to their Regulatory Authorities, and/or for publication. The data protection laws in these countries can be different, but all parties involved in this process have a duty to protect your identity and use the data for legitimate healthcare purposes only. If your data is sent to third parties, all appropriate measures will be taken to ensure your data is protected. You have the right to request access to, and information about the handling of your personal health information from the study doctor. To ensure proper evaluation of test results, your access to these study results may not be allowed until after the study is completed. You may request correction of data if they are inaccurate or incomplete and to restrict use of data while it is being corrected.

In the case that you are unable to pick up from the local pharmacy and study drug is delivered to you, the approved vendor and its contractors will need to collect and process certain information about you including your name, home or alternate shipping address, and telephone number. The approved vendor and its contractors will be required to keep your information private, and not share it with anyone else.

6. What happens if I am injured or hurt during the 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 him/her at the number(s) listed above.

If you feel you have been 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 the study sponsor, Amgen, 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) 824-6068 or (949) 824-2125 or by e-mail at IRB@research.uci.edu

If the study sponsor covers these costs they will need to know some information about you like your name, date of birth, and Medicare Health Insurance Claim Number, or, if you do not have one, your Social Security Number. This information will be used to check to see if you receive Medicare, and, if you do, report the payment they make to Medicare. The study sponsor will not use this information for any other purpose.

OTHER ISSUES TO CONSIDER WHEN DECIDING WHETHER TO PARTICIPATE IN THISSTUDY

Public Information about this Study:
ClinicalTrials.gov is a website that provides information about federally and privately supported clinical trials.

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

Investigator Financial Conflict of Interest
None of the study team have a financial conflict of interest to disclose.

Use of Research Specimens
Any specimens (e.g., tissue, blood, urine) obtained for the purposes of this study will be provided to the Sponsor of this study, Amgen. Once you provide the specimens you may not have access to them. Use of the specimens could result in discoveries that could become the basis for new products or therapeutic agents. In some instances, these discoveries may be of potential commercial value. You will not receive any money or other benefits derived from such a product.

7. Who do I call if I have questions?

Contact the research team listed at the top of this form during office hours for any of the following reasons:

- if you have any questions about your participation in this study,
- if you feel you have had a research-related injury or a reaction to the study drug, or
- if you have questions, concerns or complaints about the research

Call the 24-hour number also listed on the top of this form at any time to report a research-related injury or a health concern possibly related to the study drug.

If you have questions about your rights as a research subject or if you have questions, concerns, input, or complaints about the research, you may contact:

WCG IRB
1019 39th Avenue SE, Suite 120
Puyallup, Washington 98374-2115
Telephone: 1-855-818-2289
E-mail: researchquestions@wcgirb.com

WCG IRB is a group of people who perform independent review of research.

WCG IRB will not be able to answer some study-specific questions, such as questions about appointment times. However, you may contact WCG IRB if the research staff cannot be reached or if you wish to talk to someone other than the research staff.

8. Consent to participate in this study and use my data

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 "Research 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.

If the research described in this form involves your protected health information (PHI), you will be asked to sign a UC HIPAA Research Authorization form authorizing the access, use, creation, and/or disclosure of your health information which is appended at the end of this form.

I agree to participate in the study.

a copy of this signed and dated informed consent form

Signature of Participant:	Date/Time:
Participant's Printed Name:	
Signature of Person Obtaining Consent:	Date/Time:
Printed Name of Person Obtaining Consent:	
Signature of Legally Authorized Representative (LAR) if applicable:	Date/Time:
LAR Printed Name:	

- ❑ I have explained the study to the extent compatible with the subject's capability, and the subject has agreed to be in the study.

OR

- ❑ The subject is not able to assent because the capability of the subject is so limited that the subject cannot reasonably be consulted.

_____ _____

Signature of person obtaining assent Date

Previously, you could not legally agree to take part in research. You took part in research based on the permission of someone else. Now that you can consent for yourself, you are being asked for your consent to continue to take part. Please read the entire document before signing below.

Your signature documents your consent to take part in this research.

Signature of adult subject capable of consent	Date
Signature of person obtaining consent	Date

A witness signature is required on this consent form only if: (Researchers: check which one applies)

☐ 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).

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

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

_____
Printed Name of Witness

Appendix A. Incapacitated Adult Assent Statement to Participate in a Research Study *(if applicable)*

Dr. Barseghian's study team has explained the research study called: EVOLVE-MI: A Pragmatic Randomized Multicenter Trial of EVOLocumab Administered Very Early to Reduce the Risk of Cardiovascular Events in Patients Hospitalized With Acute Myocardial Infarction to me.

_____ (*print participant name)* is unable to give consent for the following reason(s): __

_____

_____

and I, the legally authorized representative, agree that _____ *(print participant name)* can participate in this study.

Signature of Legally Authorized Representative (LAR):	Date/Time:
LAR Printed Name:	
Signature of Person Obtaining Consent/ Assent:	Date/Time:
Printed Name of Person Obtaining Consent/ Assent:	

A witness signature is required on this consent form only if: (Researchers: check which one applies)

☐ 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).

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

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**

(If no witness signature is required, this witness signature section of the consent form may be left blank).

_____
Printed Name of Witness

UNIVERSITY OF CALIFORNIA, IRVINE
Research 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 study team listed at the top of the consent form.

I can also contact the WCG IRB, Inc. which helps protect research study participants. I can reach the WCG IRB, Inc by calling 855-818-2289 from 8:00 AM to 5:00 PM, Monday to Friday. If I call this office and do not speak English or Spanish, I should have someone available who can interpret for me. I may also write to WCG IRB, Inc., 1019 39th Avenue SE Suite 120, Puyallup, WA 98374-2115. To get a copy of the bill of rights I may contact the research team or go to **https://research.uci.edu/wp-content/uploads/experimental-subjects-b-o-r.docx**