UNIVERSITY OF CALIFORNIA LOS ANGELES
CONSENT TO PARTICIPATE IN RESEARCH

Study title: "Biologic Therapy to Prevent Osteoarthritis After ACL Injury"

Lay title: "Injection of naturally occurring protein into the knee after ACL injury to prevent arthritis in the future"

INTRODUCTION

Thomas Kremen, M.D. and associates from the Department of Orthopaedic Surgery at the University of California, Los Angeles (UCLA) is conducting a research study.

The researchers will explain this study to you. **Research studies are voluntary and include only people who choose to take part.** Please take your time about deciding whether to participate in this study. Before deciding:

- You can discuss this study with friends and family.
- You can also discuss it with your health care doctor or request a second opinion.
- If you have any questions, you can ask the researchers for more information before deciding to participate.

The research team is asking you to be in this study because you have recently suffered an anterior cruciate ligament (ACL) injury and are at risk of developing early osteoarthritis in your injured knee as a result of this injury.

WHY IS THIS STUDY BEING DONE?

ACL injury causes inflammation in the knee joint. This inflammation is believed to cause an increase in arthritis in your knee many years after the injury itself. One of the main factors controlling this inflammation is a molecule called Interleukin-1. This research study is trying to determine if injecting the medication anakinra (a naturally occurring human protein known to inhibit Interleukin-1) into the knee joint after ACL injury can reduce the risk of arthritis in the future.

Anakinra is a well-characterized human protein synthesized by a pharmaceutical company. This naturally occurring human protein is normally found in the knee after injury, however the amount of this protein is relatively low. This medication was originally developed to treat patients with rheumatoid arthritis. It is FDA approved for injection under the skin of patients with rheumatoid arthritis in order to decrease the inflammation in their bodies. In this research study the medication will be injected into your knee joint to try to temporarily decrease the inflammation in your knee. Since the route of administration is new (i.e. we are injecting your knee joint rather than under your skin), this procedure is considered investigational.

The following definitions may help you understand how this research study is designed:

Randomized: participants are assigned to receive a certain type of treatment. For example, one group of participants will receive an injection of medication into their knee called anakinra and another group of participants will receive an injection of salt water into their knee (placebo). Determining which treatment you receive will be random, like flipping a coin to decide which group to which you are assigned.
Placebo: a substance without harmful effects that has no known therapeutic effect, used as a control in testing new drugs.
Hemarthrosis: blood that collects in your knee joint after injury
Aspiration: removing fluid from the body using a needle and syringe
Arthrocentesis: removing fluid specifically from a joint in the body using a needle and syringe
Saline: salt water that contains sodium and chloride ions at the same concentration that exists in our blood.
Standard of care: refers to a treatment course that would be considered consistent with best practice clinical treatment guidelines
Anakinra: also known as kineret, a human protein synthesized by a pharmaceutical company that naturally inhibits the activity of interleukin-1. By doing this, it helps reduce inflammation.
Interleukin-1: a molecule in the body that regulates inflammation.
ACL: anterior cruciate ligament, a ligament in the center of the human knee that provides stability to the knee.

This study is being funded by the Orthopaedic Research and Education Foundation.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

32 people will take part in this study at UCLA.

WHAT WILL HAPPEN IF I TAKE PART IN THIS STUDY?

Before you begin the study:
Before you begin the study, you will need to have your knee examined by a doctor and undergo an MRI demonstrating a recent tear of your ACL. This MRI can be done at a facility outside of UCLA (i.e. an MRI not performed at a UCLA-affiliated imaging center). This MRI is performed for your standard of care for treatment of your ACL. We will ask you to bring a copy of your MRI images during the screening visit because we will use the findings of this MRI to confirm your eligibility for this study.

During the study:
If you take part in this study, you will be randomized to one of 2 equal sized treatment groups included in this study (see groups below). The probability of being assign to any one of these groups is 50%. The probability of receiving the study drug (anakinra) is 50%. Each treatment group will receive two injection procedures prior to surgery. Then they will undergo ACL reconstruction surgery using their own patellar tendon and bone tissue performed using standard technique. At the time of surgery and at the first clinic visit after surgery, a sample of your knee joint fluid will also be collected.

Study Drug and Synovial Fluid Collection:

1. Group 1 will include 16 participants. These participants will receive aspiration of the fluid in the knee joint at the time of their initial clinic visit. This procedure will also be completed again at 3-5 days after the initial study visit. Removing this excess knee fluid (a.k.a hemarthrosis) is a common practice after ACL injury. Following aspiration of the excess knee joint fluid, an injection of approximately 5 milliliters (mls, 1 teaspoon) of sterile saline (salt water) as a placebo control will be administered. In addition, a second aspiration of the knee joint and injection of 5mls of sterile saline into the injured knee joint will be performed 3 - 5 days after initial injection of sterile saline.

2. Group 2 will also include 16 participants who will receive aspiration of the excess fluid in the knee joint and injection of anakinra at the time of their initial clinic visit as described in group 1 as well as a second aspiration of the excess knee joint fluid and injection of anakinra (150mg, ~1.5mls) diluted in sterile saline (~3.5mls) 3 - 5 days after initial injection of anakinra.

Regardless of the treatment group to which you are randomized, all participants will undergo two aspiration and injection procedures of the injured knee prior to surgery. The first injection will be after an arthrocentesis procedure to remove the excess knee joint fluid (hemarthrosis) associated with acute ACL injury as is standard of care. To minimize pain and discomfort the same needle stick will be used to aspirate the knee joint fluid and to inject the sterile saline or anakinra depending on each participant's treatment group. The second arthrocentesis and injection procedure in each participant will be performed at 3 – 5 days after initial injection. An additional arthrocentesis procedure will be performed at the time of surgery while you are already under anesthesia (administered sedation and asleep prior to any knee aspiration procedure). Of note, if no fluid is able to be aspirated from the knee joint after the initial aspiration at any of the timepoints, then joint fluid may not be obtained.

MRI including Cartilage-Sensitive Sequences:

You will be asked to undergo MRIs of your knee at 3 different time points for the study: within 3 weeks of injury, 12 months post-surgery, and 24 months post-surgery. If we are unable to collect the MRI within 3 weeks of your injury, we will also obtain ascan MRI of your uninjured knee in addition to your injured knee at the 12-month post-surgery timepoint and the 24-month post-surgery timepoint.

Urine Collection:

You will also be asked to donate urine to test for markers of cartilage injury, all timepoints are listed in the Schedule of Study Procedures table in page 4. Urine will be collected using a sterile container. We can give you these containers to take home or you can donate a sample in the restroom located in the UCLA Orthopaedic Clinic.

Survey Collection:

You will be asked to complete a survey regarding your knee function, pain, and symptoms. All timepoints are listed in the Schedule of Study Procedures table below.

Schedule of Study Procedures									
	V1	**V2**	**V3**	**V4**	**V5**	**V6**	**V7**	**V8**	**V9**
Time point	Within 2 weeks after ACL injury	3-5 days after initial injection	Within 45 days after ACL injury (Day of Surgery)	8-10 days after surgery	Post-Surgery Month 3	Post-Surgery Month 6	Post-Surgery Month 9	Post-Surgery Month 12	Post-Surgery Month 24
Informed Consent	X								
Anakinra or Placebo Treatment	X	X							
Synovial fluid collection (Aspiration)	X	X	X	X					
Urine Collection	X	X	X	X	X	X	X	X	X
MRI including cartilage-sensitive sequences*	X* *(within 3 weeks of injury)*							X	X
BTB autograft ACL reconstruction surgery (Standard of Care)			X						
Survey Completion	X					X	X	X	X

**Cartilage-sensitive MRI: When available, T1rho MRI imaging will be obtained at pre-operatively within 3 weeks of injury. However, due to time constraints and research MRI scanner availability, T1rho magnetic resonance (MR) image sequences are currently not always able to be obtained pre-operatively in the short time window between participant injury and participant enrollment into the study. This portion of the study will also depend on availability of the special cartilage sensitive MRI machine.*

This study will be a single-blinded design. This means that the study physician performing the injection will not be blinded with regard to which participants receive

study drug (Anakinra) treatments. However, you, the participant, will be blinded regarding which treatment you receive. All participants will receive injections of the same volume and using the same type of needle and syringe. In addition, the radiologist interpreting the MRI studies will be blinded to which treatment the participants receive. The study physician administering the injections into the joint will not be involved in interpreting the MRI findings and will not be present when you complete the surveys. In addition, the synovial fluid and urine biomarker data will be analyzed in a coded fashion in conjunction with a statistician to avoid bias in the statistical analysis.

You will not receive any results from this study. However, if significant knee structural pathology is discovered you will be referred to a Sports Medicine Physician for evaluation.

HOW LONG WILL I BE IN THIS STUDY?

This study will last 2 years. This is about 1 year longer than the average patient with an ACL injury continues to follow up with their surgeon.

WHAT KINDS OF RISKS OR DISCOMFORTS COULD I EXPECT?

Known risks and discomforts:
The possible risks and/or discomforts associated with the various procedures described in this consent form are included below. These risks are subdivided by the procedure with which they are associated.

- Intra-articular injection of sterile saline or anakinra
    - The injection procedure will have associated discomfort similar to any knee injection procedure. Of note, the aspiration and injection of saline or anakinra will be performed through one needlestick.
    - As with all injections, there is a possible risk of knee infection. The injection will be performed using sterile technique and the risk of infection from the injection procedure is much less than 1%.
- Additional risks of intra-articular injection of anakinra
    - Given that anakinra can inhibit the inflammation in the joint, there is also a theoretic higher risk of joint infection when compared to any other joint injection. However, given that the joint will be injected under standard sterile conditions, the risk of this is thought to be very low." In addition, an injection of 150mg of Anakinra, as proposed in this study, has been performed in two separate trials in the past in which no adverse reactions have been reported.
    - There is also an extremely small risk that you will have an allergic reaction to this medication, particularly if you have not been exposed to this medication previously, the risk of allergic reaction is much less than 0.1%
- Knee hemarthrosis aspiration (removal of the blood in your knee using a needle and syringe)
    - The aspiration procedure will have associated discomfort similar to any knee injection procedure. Of note, the aspiration and injection of saline or anakinra will be performed through one needlestick.

    - As with all injections, there is a possible risk of knee infection. The injection will be performed using sterile technique and the risk of infection is much less than 1%.
- MRI scan
    - MRI scans may cause some claustrophobia/anxiety, however, knee MRIs allow for feet first entry into the MRI scanner such that your head is not enclosed in the scanning bay. This decreases the risk of associated claustrophobia symptoms.
    - MRI scan is associated with a loud knocking or buzzing noise and the participant will be provided with earplugs or headphones to reduce the noise.

When Anakinra is given repeatedly as an injection under the skin for treatment of patients with rheumatoid arthritis, it has been associated with an increase in serious infections and a decrease in white blood cells that fight infections. Because you would be receiving, at most, only one or two injections into the knee joint, we believe that these side effects are very unlikely.

Unknown risks and discomforts:
The experimental treatments may have side effects that no one knows about yet. The researchers will let you know if they learn anything that might make you change your mind about participating in the study.

ARE THERE ANY BENEFITS IF I PARTICIPATE?

Possible benefits to me:
The possible benefits you may experience from being in this study include the potential for a decreased risk of osteoarthritis affecting your knee later in life.

Possible benefits to others or society:
This study will also help the researchers learn more about how anakinra may help prevent osteoarthritis from occurring in ACL-injured patients in the future. The results of the research may, ultimately, lead to improved long-term functional outcomes among ACL-injured patients (better knee function) as well as limit the substantial healthcare costs associated with the treatment of post-traumatic osteoarthritis after ACL injury. Currently about 50% of patients who suffer an ACL injury will develop osteoarthritis 10 to 20 years after their injury.

WHAT OTHER CHOICES DO I HAVE IF I DON'T WANT TO PARTICIPATE?

If you decide not to take part in this study, or if you withdraw from this study before it is completed, the following alternative procedures or courses of treatment are available: The standard of care for all ACL injury patients. This includes either surgical treatment

or non-surgical treatment options. Both surgically treated and non-surgically treated patients can receive aspiration of their hemarthrosis (blood in the joint) associated with ACL injury in the acute period after injury (within ~1 week after injury). Non-surgical treatment would consist of physical therapy and activity modification (avoiding cutting and pivoting activities). Surgical treatment would consist of ACL reconstruction followed by physical therapy without any injection of anakinra medication into the knee joint.

HOW WILL INFORMATION ABOUT ME AND MY PARTICIPATION BE KEPT CONFIDENTIAL?

The researchers will do their best to make sure that your private information is kept confidential. Information about you will be handled as confidentially as possible, but participating in research may involve a loss of privacy and the potential for a breach in confidentiality. Study data will be physically and electronically secured. As with any use of electronic means to store data, there is a risk of breach of data security.

Use of personal information that can identify you:
Subject identifiers will not be placed on specimens collected in this study. Unique identifiers in the form of medical record numbers (MRNs) in the UCLA CareConnect electronic medical record system will be stored in an excel file on a firewall-protected, encrypted UCLA-owned computer that will remain on campus behind a locked door at all times. This information will be transferred into a coding scheme for any data analysis that takes place and as a result of this coding process all subject unique identifiers will be removed. After data analysis, your name and medical record number will be stored in a secure HIPAA-compliant network that only the study team will have access to. The study team will keep this information so that the study team may invite you to participate in optional follow up studies in the future, and if you agree you may be asked to sign a separate consent form.

How information about you will be stored:
Unique identifiers in the form of medical record numbers (MRNs) in the UCLA CareConnect electronic medical record system will be stored in an excel file on a firewall-protected, encrypted UCLA-owned computer that will remain on campus behind a locked door at all times. If any data is needed to be accessed (e.g. statistical analysis), it will be transferred to a coded-format without unique identifiers. The decoding scheme will be stored on the same firewall-protected, UCLA-owned computer that will remain on campus behind a locked door at all times.

People and agencies that will have access to your information:
The research team, authorized UCLA personnel, the study sponsor and regulatory agencies such as the Food and Drug Administration (FDA), may have access to study data and records to monitor the study. Research records provided to authorized, non-UCLA personnel will not contain identifiable information about you. Publications and/or presentations that result from this study will not identify you by name.

How long information from the study will be kept:

The researchers intend to keep the research data, specimens, and records indefinitely for future research.

ARE THERE ANY COSTS FOR TAKING PART IN THIS STUDY?

The study will pay for research-related items and/or services that are provided only because you are participating in the study. These research-related items and/or services are explained in other areas of this consent form.
You or your health plan may be responsible to pay for all the types of items listed below:

- Items and services that would have been provided to you even if you were not in the study
- Health care given during the study as part of your regular care
- Items or services needed to give you study drugs or devices
- Monitoring for side effects or other problems
- Deductibles or co-pays for these items and/or services

WILL I BE PAID FOR MY PARTICIPATION?

You will not be paid for your participation in this research study.

WHAT OTHER THINGS SHOULD I CONSIDER BEFORE PARTICIPATION?

Use of My Specimens:
Any specimens (e.g., tissue, blood, urine) obtained for the purposes of this study will become the property of the University of California. Once you provide the specimens you will not have access to them. The University may share your specimens in the future with other researchers or outside institutions. Information that identifies you will not be shared with anyone outside of UCLA. The specimens will be used for research and such use may result in inventions or discoveries that could become the basis for new products or diagnostic or therapeutic agents. In some instances, these inventions and discoveries may be of potential commercial value and may be patented and licensed by the University. You will not receive any money or other benefits derived from any commercial or other products that may be developed from use of the specimens

WHO CAN I CONTACT IF I HAVE QUESTIONS ABOUT THIS STUDY?

The Research Team:
You may contact Thomas Kremen, M.D. at 424-259-9856 with any questions or concerns about the research or your participation in this study. You can also call the UCLA Page Operator at (310) 825-6301 to reach Thomas Kremen, M.D. 24 hours a day, 7 days week.

UCLA Office of the Human Research Protection Program (OHRPP):
If you have questions about your rights while taking part in this study, or you have concerns or suggestions and you want to talk to someone other than the researchers

about the study, you may contact the UCLA OHRPP by phone: (310) 825-5344; by email: mirb@research.ucla.edu or U.S. mail: UCLA OHRPP, 11000 Kinross Ave., Suite 211, Box 951694, Los Angeles, CA 90095-1694.

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 website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

WHAT HAPPENS IF I BELIEVE I AM INJURED BECAUSE I 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 him/her at the number(s) listed above.

If you are injured as a result of being in this study, UCLA will provide necessary medical treatment. The costs of the treatment may be covered by the University of California or the study sponsor Orthopaedic Research and Education Foundation 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 the UCLA Office of the Human Research Protection Program at 310-825-5344 or send an email to mirb@research.ucla.edu.

WHAT ARE MY RIGHTS IF I TAKE PART IN THIS STUDY?

Taking part in this study is your choice. You can choose whether or not you want to participate. Whatever decision you make, there will be no penalty to you and you will not lose any of your regular benefits.

- You have a right to have all of your questions answered before deciding whether to take part.
- Your decision will not affect the medical care you receive from UCLA.
- If you decide to take part, you can leave the study at anytime.
- If you decide to stop being in this study you should notify the research team right away. The researchers may ask you to complete some procedures in order to protect your safety.
- If you decide not to take part, you can still get medical care from UCLA.

HOW DO I INDICATE MY AGREEMENT TO PARTICIPATE?

If you agree to participate in this study you should sign and date below. You have been given a copy of this consent form and the Research Participant's Bill of Rights to keep. You will be asked to sign a separate form authorizing access, use, creation, or disclosure of health information about you.

SIGNATURE OF THE PARTICIPANT

_____
Name of Participant

_____ _____
Signature of Participant Date

SIGNATURE OF PERSON OBTAINING CONSENT

_____ _____
Name of Person Obtaining Consent Contact Number

_____ _____
Signature of Person Obtaining Consent Date

IRB# 19-000724

University of California Los Angeles
(Name of Your Health System) [1]

Permission to Use Personal Health Information for Research

Study Title (or IRB Approval Number if study title may breach subject's privacy):
19-000724

Principal Investigator Name:

Thomas Kremen, MD

Sponsor/Funding Agency (if funded):

ORTHOPAEDIC RESEARCH & EDUCATION FOUNDATION

A. What is the purpose of this form?

State and federal privacy laws protect the use and release of your health information. Under these laws, the University of California or your health care provider cannot release your health information for research purposes unless you give your permission. Your information will be released to the research team which includes the researchers, people hired by the University or the sponsor to do the research and people with authority to oversee the research. If you decide to give your permission and to participate in the study, you must sign this form as well as the Consent Form. This form describes the different ways that the UCLA Health (Name of Health System Component) [2] can share your information with the researcher, research team, sponsor and people with oversight responsibility. The research team will use and protect your information as described in the attached Consent Form. However, once your health information is released by UCLA Health (Name of Heath System) [3] it may not be protected by the privacy laws and might be shared with others. If you have questions, ask a member of the research team.

B. What Personal Health Information will be released?

If you give your permission and sign this form, you are allowing: Dr. Thomas Kremen, MD (Doctor's Name) to release the following medical records containing your Personal Health Information. Your Personal Health Information includes health information in your medical records, financial records and other information that can identify you.

[1] Each UC Health System or business unit may elect to leave this as UC or add the name of their specific health system or unit.
[2] The name here should match how the organization is identified in the Notice of Privacy Practices.
[3] The name here should match how the organization is identified in the Notice of Privacy Practices.

- ■ Entire Medical Record
- ☐ Ambulatory Clinic Records
- ☐ Progress Notes
- ☐ Other Test Reports
- ☐ Other (describe)

_____
(Description of Other Health Information)

- ☐ Lab & Pathology Reports
- ☐ Dental Records
- ☐ Operative Reports
- ☐ Discharge Summary
- ☐ Consultations

- ☐ Emergency Department Records
- ☐ Financial Records
- ☐ Imaging Reports
- ☐ History & Physical Exams
- ☐ Psychological Tests

C. Do I have to give my permission for certain specific uses?

Yes. The following information will only be released if you give your specific permission by putting your initials on the line(s).

_____I agree to the release of information pertaining to drug and alcohol abuse, diagnosis or treatment.

_____I agree to the release of HIV/AIDS testing information.

_____I agree to the release of genetic testing information.

_____I agree to the release of information pertaining to mental health diagnosis or treatment.

D. Who will disclose and/or receive my Personal Health Information?

Your Personal Health Information may be shared with these people for the following purposes:

1. To the research team for the research described in the attached Consent Form;
2. To others at UC with authority to oversee the research
3. To others who are required by law to review the quality and safety of the research, including: U.S. government agencies, such as the Food and Drug Administration or the Office of Human Research Protections, the research sponsor ORTHOPAEDIC RESEARCH & EDUCATION FOUNDATION (Sponsor Name) or the sponsor's representatives including but not limited to n/a (CRO Name), or government agencies in other countries.

E. How will my Personal Health Information be shared for the research?

If you agree to be in this study, the research team may share your Personal Health Information in the following ways:

1. To perform the research
2. Share it with researchers in the U.S. or other countries;
3. Use it to improve the design of future studies;
4. Share it with business partners of the sponsor; or

5. File applications with U.S. or foreign government agencies to get approval for new drugs or health care products.

F. Am I required to sign this document?

No, you are not required to sign this document. You will receive the same clinical care if you do not sign this document. However, if you do not sign the document, you will not be able to participate in this research study.

G. Optional research activity

If the research I am agreeing to participate in has additional optional research activity such as the creation of a database, a tissue repository or other activities, as explained to me in the informed consent process, I understand I can choose to agree to have my information shared for those activities or not.

☐ I agree to allow my information to be disclosed for the additional optional research activities explained in the informed consent process.

H. Does my permission expire?

This permission to release your Personal Health Information expires when the research ends and all required study monitoring is over.

I. Can I cancel my permission?

You can cancel your permission at any time. You can do this in two ways. You can write to the researcher or you can ask someone on the research team to give you a form to fill out to cancel your permission. If you cancel your permission, you may no longer be in the research study. You may want to ask someone on the research team if canceling will affect your medical treatment. If you cancel, information that was already collected and disclosed about you may continue to be used for limited purposes. Also, if the law requires it, the sponsor and government agencies may continue to look at your medical records to review the quality or safety of the study.

J. Signature

Subject

If you agree to the use and release of your Personal Health Information, please print your name and sign below. You will be given a signed copy of this form.

_____

Subject's Name (print)—*required*

_____ _____

Subject's Signature Date

Parent or Legally Authorized Representative

If you agree to the use and release of the above named subject's Personal Health Information, please print your name and sign below.

Parent or Legally Authorized Representative's Name (print)	Relationship to Subject
Parent or Legally Authorized Representative's Signature	Date

Witness

If this form is being read to the subject because s/he cannot read the form, a witness must be present and is required to print his/her name and sign here:

Witness' Name (print)	
Witness' Signature	Date

UNIVERSITY OF CALIFORNIA LOS ANGELES

RESEARCH PARTICIPANT'S

BILL OF RIGHTS

These rights are the rights of every person who is asked to be in a medical research study. As a research participant, I have the following rights:

1. I have the right to be told what the research is trying to find out.

2. I have the right to be told about all research procedures, drugs, and/or devices and whether any of these are different from what would be used in standard practice.

3. I have the right to be told about any risks, discomforts or side effects that might reasonably occur as a result of the research.

4. I have the right to be told about the benefits, if any, I can reasonably expect from participating.

5. I have the right to be told about other choices I have and how they may be better or worse than being in the research. These choices may include other procedures, drugs or devices.

6. I have the right to be told what kind of treatment will be available if the research causes any complications.

7. I have the right to have a chance to ask any questions about the research or the procedure. I can ask these questions before the research begins or at any time during the research.

8. I have the right to refuse to be part of the research or to stop at any time. This decision will not affect my care or my relationship with my doctor or this institution in any other way.

9. I have the right to receive a copy of the signed and dated written consent form for the research.

10. I have the right to be free of any pressure as I decide whether I want to be in the research study.

If I have any questions or concerns I can ask the researcher or the research assistant. I can also contact the Office of the Human Research Protection Program (OHRPP), which helps protect research study participants. I can reach the OHRPP by calling 310-825-5344 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 OHRPP, 11000 Kinross Avenue, Suite 211, Box 951694, Los Angeles, CA 90095-1694.

4/10

Researchers: Call 310-825-5344 for translations or information about using this form as part of the "short form" process.