***IMPORTANT: ALL SECTIONS ARE REQUIRED UNLESS OTHERWISE NOTED. BEFORE FINALIZING & UPLOADING THIS DOCUMENT: REMOVE: THIS PARAGRAPH & ALL [RED INSTRUCTIONAL TEXT].***

UNIVERSITY OF CALIFORNIA, IRVINE

**INFORMED CONSENT DOCUMENT FOR EXPANDED ACCESS OF**

**AN INVESTIGATIONAL DRUG OR DEVICE**

When a patient has a serious or life-threatening condition that is not addressed by current approved treatments, options may exist to use an investigational drug, biologic or medical device (i.e., one that has not been approved or cleared by Food and Drug Administration (FDA) to treat the patient. Normally, such investigational agents with significant risks may only be used on human subjects through an FDA-approved clinical trial. However, there are circumstances under which a health care provider may use an investigational device outside of a clinical study to save the life of a patient or to help a patient suffering from a serious disease or condition for which no other alternative therapy exists. The use of an investigational agent outside of a clinical trial for treatment of a patient is called “Expanded Access” (sometimes referred to as “Compassionate Use”).

For investigational drugs, Expanded Access may involve a single patient (including emergency use), an intermediate or a widespread population under an Investigational New Drug (IND). For investigational devices, Expanded Access includes the use of an investigational device on a single patient (including emergency use), small group access and treatment use population under an Investigational Device Exemption (IDE).

By signing below, you consent to receive this investigational agent. Although it is hoped that your condition will be improved by this treatment, no guarantees can be offered when using this investigational drug or device. **You do not have to agree to this treatment. Treatment is completely voluntary.**

Please read the information below and ask questions about anything that you do not understand.

**(*Note that if you are providing consent for your child or are the legal representative, surrogate or next-of-kin for the individual who is to receive this emergency treatment, “you” in this form refers to the individual receiving treatment.)* *[If not applicable, please remove]***

**Treating Physician: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Department: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Phone Number: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Pager Number: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Patient Initials: Age: \_\_\_\_\_\_\_\_\_\_\_\_**

**Name of Investigational Drug or Biologic: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**PURPOSE OF THE INVESTIGATIONAL TREATMENT**

You are being told about this treatment because [specify the patient’s condition and available treatments]. [Name of drug or device] has not received approval for use in treating [indication] from the Food and Drug Administration (FDA). Research studies to see how safe and how well this [drug or device] treats diseases may be happening, but you are getting this to treat your condition. The use of[Name of drug or device] is for clinical purposes, not research.

**PROCEDURES INVOLVED WITH THE USE OF THE INVESTIGATIONAL TREATMENT**

[Describe the procedures in chronological order.]

**HOW LONG WILL THIS TREATMENT LAST?**

[Describe the length of time treatment will entail – include number of visits or treatments, as applicable.]

**POTENTIAL RISKS OF TREATMENT**

Because this treatment is considered investigational and has not received FDA approval, there may be risks that we do not know about at this time. The known risks/side effects are listed below.

[List reasonably forseeable risks of the drug or device. Include frequency if known.]

**POTENTIAL BENEFITS OF TREATMENT**

Taking part in this treatment may or may not improve your health. While your medical team hopesthat the *[procedures/ drugs/ interventions/ devices]* will help, there is no proof of this yet.

[List reasonably foreseeable benefits of the drug or device. Include frequency if known.]

**ALTERNATIVE TREATMENT OPTIONS**

You may chose not to receive this investigational treatment or may stop treatment at any time. Your decision will not affect the quality of care you receive at the UCI Medical Center. Your doctor, as well, may discontinue the investigational treatment if she/he feels it is in your best interest.

If you do not agree to this treatment or if the treatment is stopped early, the following alternatives are available to you:

**WHAT WILL THE INVESTIGATIONAL TREATMENT COST?**

[The [drug or device] will be provided free of charge to you.]

 *or*

[The cost of      is      .]

Your insurance plan may or may not pay for treatment with this [drug or device]. If your insurance plan does not pay for this treatment, you will be billed for the cost of the [drug or device] and all related doctor and hospital costs. The total of these charges depends on your specific treatment needs but the average cost of this type of treatment is $     .

**WHO WILL PAY FOR MEDICAL CARE IF YOU ARE INJURED BECAUSE OF THIS TREATMENT?**

It is important that you promptly tell the physician / your doctor listed on this consent form if you believe that you have been injured because of this treatment.  You can tell your doctor in person or call him/her at the numbers listed at the top of this form.

If you are injured as a result of this treatment, the costs of the treatment will be billed to you or your insurer just like other medical costs. For more information about this, you should talk to your doctor.

**CONFIDENTIALITY**

All information about your treatment with [Name of drug or device] will be kept in your medical record and will be kept for an unknown length of time.

If you agree to receive [Name of drug or device], your doctor may share information about your condition with authorized UCI personnel and regulatory entities such as the Food and Drug Administration (FDA) and the Office for Human Research Protections. Any information derived from this investigational treatment that personally identifies you will not be voluntarily released or disclosed by these entities without your separate consent, except as specifically required by law. Records provided to authorized, non-UCI entities will not contain identifiable information about you. Any results from your treatment with [Name of drug or device] will not include identifiable information about you.

[*Per FDA, this language will be required for clinical trials – and expanded access protocols approved by the IRB on or after March 7, 2012. Although the language is optional for new studies approved before that date, sponsor may request the language. This language must be included verbatim. Note: Reporting results to ClinicalTrials.gov is not necessary for any of the 3 types of Expanded Access.*]

ClinicalTrials.gov is a Web site that provides information about 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.

**NEW FINDINGS**

If, during the course of this investigational treatment with [Name of drug or device], significant new information becomes available that may relate to your willingness to continue to treatment, this information will be provided to you by your doctor.

**IF YOU HAVE QUESTIONS**

If you have any comments, concerns, or questions regarding your treatment, please contact your doctor at the numbers listed at the top of this form.

If you are unable to reach your doctor or have general questions or concerns about your rights as a patient receiving Emergency or Expanded Access treatment, please contact UCI’s Office of Research by phone at (949) 824-8170 or by e-mail at IRB@research.uci.edu.

**PATIENT CONSENT**

You should not sign this form unless you have read the attached “Patient Bill of Rights” form. [*Physicians please provide the patient with copy of the current version of the UCI Health Patient Bill of Rights]*  **Receipt of this Expanded Access treatment is voluntary.**  You may refuse to accept this investigational treatment or discontinue treatment at any time without penalty or loss of benefits to which you might otherwise be entitled. Your decision will not affect your quality of care at the UCI Medical Center. Your signature below indicates that you have read the information in this consent form and have had a chance to ask any questions that you have about the Emergency Use treatment.

You will receive a copy of this consent form to keep.

***I have read this consent form and the treatment plan has been explained to me verbally. All my questions have been answered, and I agree to receive the investigational treatment described above.***

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**PATIENT - *AGE 7 AND OLDER* (print name)**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**SIGNATURE DATE**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**LEGALLY AUTHORIZED REPRESENTATIVE OF PATIENT RELATIONSHIP TO PATIENT**

**(print name)**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**SIGNATURE DATE**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**LEGALLY AUTHORIZED REPRESENTATIVE OF PATIENT RELATIONSHIP TO PATIENT**

**(print name)**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**SIGNATURE DATE**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**INVESTIGATOR (print name)**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**SIGNATURE DATE**

**UNIVERSITY OF CALIFORNIA, IRVINE**

**Experimental Subject's Bill of Rights**

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

1. To be told about the nature and purpose of the study.
2. To be told about the procedures to be followed in the research study, and whether any of the drugs, devices, or procedures is different from what would be used in standard practice.
3. To receive a description of any side effects, discomforts, or risks that you can reasonably expect to occur during the study.
4. To be told of any benefits that you may reasonably expect from the participation in the study, if applicable.
5. To receive a description of any alternative procedures, drugs, or devices that might be helpful, and their risks and benefits compared to the proposed procedures, drugs or devices.
6. To be told of what sort of medical treatment, if any, will be available if any complications should arise.
7. To be given a chance to ask any questions concerning the research study both before agreeing to participate and at any time during the course of the study.
8. To refuse to participate in the research study. Participation is voluntary. You may refuse to answer any question or discontinue your involvement at any time without penalty or loss of benefits to which you might otherwise be entitled. Your decision will not affect your right to receive the care you would receive if you were not in the experiment.
9. To receive a copy of the signed and dated written consent form and a copy of this form.
10. To be given the opportunity to freely decide whether or not to consent to the research study without any force, coercion, or undue influence.

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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.