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| **or-logo-stacked** | **Treatment with an Investigational Drug or Biologic Under Right to Try (RTT) Laws***Version 10-04-2023* |

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| **Treating Physician Checklist** |

1. **CONFIRM DRUG APPLICABILITY CRITERIA:**
2. The investigational drug or biologic has successfully completed a Phase I clinical trial. [[1]](#footnote-1)
3. The drug or biologic is under investigation in a clinical trial.
4. The drug or biologic is actively being developed/produced by the manufacturer OR not placed on clinical hold.
5. **CONFIRM THAT THE PATIENT MEETS THE FOLLOWING CRITERIA:**
	1. The patient has an *immediately* life-threatening disease or condition (a stage of disease in which there is a reasonable likelihood that death will occur in a matter of months).
	2. The patient has exhausted all other approved treatment options currently approved by the FDA. The patient has not been accepted to participate in the nearest clinical trial to his or her home for the immediately life-threatening disease within one week of completion of the clinical trial application process, or, in the treating physician’s medical judgment, it is unreasonable for the patient to participate in that clinical trial due to the patient’s current condition and stage of disease.
6. **SEEK IRB APPROVAL OF CONSENT AND DOCUMENT. GATHER THE FOLLOWING DOCUMENTS:**
7. Treatment Plan, include the cost of treatment.
8. Draft a Consent Form – template available at: <https://research.uci.edu/forms/index.html> (see sub-section ‘Human Research Protections’ and then ‘Consent Forms.’
9. Review and sign Treating Physician Attestation.
10. Submit Documentation to the IRB through the IRB Application process.
11. You will need to secure signature on the Consulting Physician Attestation before treatment begins.
12. Notify UCI Chief Medical Officer of RTT request.
13. **OTHER TREATING PHYSICIAN RESPONSIBILITIES:**
	1. Consult with Clinical Trials Team in Sponsored Projects Administration to determine whether an agreement is necessary with the sponsor/manufacturer.
	2. Consult with Research Revenue Integrity (RRI) to determine billing implications.
	3. Consult with Investigational Drug Services pharmacy to determine drug requirements.
	4. Ensure patient understands financial and health care considerations outlined in consent form.
	5. Register the patient in OnCore, as determined by RRI.
14. **FOLLOW UP WITH IRB. PROVIDE THE FOLLOWING WITHIN 30 DAYS OF BEGINNING OF TREATMENT:**
	1. **Provide the following to** **IRB@research.uci.edu****. Indicate “Right to Try Follow Up” in the subject line. Please do not include any patient identifiable information. Please do not include any Protected Health Information (PHI).**
		1. Provide a copy of the signed attestation.
		2. Provide the following status as required to reporting to the State Department of Public Health, the Medical Board of California, and the Osteopathic Medical Board of California:
			1. The duration of the treatment.
			2. The costs of the treatment paid by eligible patients.
			3. The success or failure of the investigational drug, biological product, or device in treating the immediately life-threatening disease or condition from which the patient suffers.
			4. Any adverse event for each investigational drug, biological product, or device.

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| **Treating Physician Attestation** |
| * **Confirm the following information and provide your signature below.**
 |
| As the Treating Physician of the Patient, I have:1. Confirmed that the investigational drug or biologic:
2. Is not yet approved by the U.S. Food and Drug Administration (FDA) for any use;
3. Has completed Phase 1 trials;
4. Remains under investigation by the FDA (i.e., a NDA or BLA has been filed with the FDA, or remains under investigation in a clinical trial); and is
5. Actively being developed/produced by manufacturer or not placed on clinical hold.
6. Examined the Patient and his/her relevant medical records and determined the Patient’s diagnosis and prognosis.
7. Verified that the Patient is an Eligible Patient as described below and is competent, acting voluntarily.

**“Eligible Patient” is a person who meets all of the following conditions:**1. Has an immediately life-threatening disease or condition, where immediate means that the Patient is in a stage of disease in which there is a reasonable likelihood death will occur in a matter of months ([Cal. Health & Safety Code § 111548.1(d)](https://leginfo.legislature.ca.gov/faces/billNavClient.xhtml?bill_id=201520160AB1668)).
2. Has considered all other treatment options currently approved by the FDA.
3. Has not been accepted to participate in the nearest clinical trial to his/her home for the immediately life-threatening disease or condition within one week of completion of the clinical trial application process; or in my medical judgment, it is unreasonable for the patient to participate in that clinical trial due to the patient’s current condition and stage of disease; and
4. As the Patient’s treating physician, I recommend that the Patient receive the investigational drug or biologic. I acknowledge that I am in good standing with the all applicable licensing organizations.
5. A Consulting Physician has completed the Consulting Physician Attestation Form.
6. Prior to providing treatment, I will confirm that the Patient:
7. Has given written informed consent for the use of the investigational drug or biologic, using the RTT Consent Form; or, if s/he lacks the capacity to consent, her/his legally authorized representative has given written informed consent on her/his behalf. NOTE: The consent document and treatment protocol must be prospectively approved by the UCI IRB.
8. Has received documentation attesting that the Patient meets the requirements of [California Health and Safety Code Article 4.5 Right to Try Act 111548.1(b).](http://leginfo.legislature.ca.gov/faces/codes_displaySection.xhtml?sectionNum=111548.1.&lawCode=HSC)

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** **Name of Treating Physician**  **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_****Signature of Treating Physician Date** |

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| **Consulting Physician Attestation** |
| * **Confirm the following information and provide your signature below.**
* Note: A “Consulting Physician” is defined as a physician and surgeon licensed under the Medical Practice Act or an osteopathic physician and surgeon licensed under the Osteopathic Act.
 |
| As I the Consulting Physician, I have:1. Examined the Patient and his/her relevant medical records.
2. Confirmed the Treating Physician’s diagnosis and prognosis.
3. Verified that the Patient is Eligible as described below and is competent, acting voluntarily.

**“Eligible Patient” is a person who meets all of the following conditions:**1. Has an immediately life-threatening disease or condition, where immediate means that the Patient is in a stage of disease in which there is a reasonable likelihood that death will occur in a matter of months ([Cal. Health & Safety Code § 111548.1(d)](https://leginfo.legislature.ca.gov/faces/billNavClient.xhtml?bill_id=201520160AB1668)).
2. Has considered all other treatment options currently approved by the United States Food and Drug Administration (FDA).
3. Has not been accepted to participate in the nearest clinical trial to his/her home for the immediately life-threatening disease or condition within one week of completion of the clinical trial application process; or in the treating physician’s medical judgment, it is unreasonable for the patient to participate in that clinical trial due to the patient’s current condition and stage of disease
4. Has received a recommendation from the Treating Physician for the use of investigational drug or biological product; and
5. As the Consulting Physician, I recommend that the Patient receive the investigational drug or biologic
6. Prior to providing treatment, I will confirm that the Patient:
7. Has given written informed consent for the use of the investigational drug or biological product; or, if s/he lacks the capacity to consent, her/his legally authorized representative has given written informed consent on her/his behalf. NOTE: The consent document and treatment protocol must be prospectively approved by the UCI IRB.
8. Has received documentation from the Treating Physician attesting that the patient meets the requirements of [California Health and Safety Code Article 4.5 Right to Try Act 111548.1(b).](http://leginfo.legislature.ca.gov/faces/codes_displaySection.xhtml?sectionNum=111548.1.&lawCode=HSC)

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** **Name of Consulting Physician**  **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_****Signature of Consulting Physician Date** |

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

**INFORMED CONSENT FOR AN ELIGIBLE PATIENT SEEKING**

**AN INVESTIGATIONAL DRUG OR BIOLOGIC UNDER RIGHT TO TRY ACT**

When a patient has an immediately life-threatening disease or condition that is not addressed by current approved treatments, options exist in the State of California through Right to Try laws to allow patients access to drugs or biologics that have not been approved by the Food and Drug Administration (FDA).

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 biologic. **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 you have been diagnosed with [specify the patient’s condition], an immediately life-threatening disease or condition. You are seeking treatment with [Name of drug or biologic] as part of the federal and California Right to Try laws. [Name of drug or biologic] has not been approved for use by the Food and Drug Administration (FDA). Early phase research with the treatment has occurred and research studies to see how safe and how well this [drug or biologic] treats diseases may be happening, but you are not eligible to participate in a clinical trial for the treatment for your condition. The use of[Name of drug or biologic] is for clinical purposes, not research.

**CURRENTLY APPROVED PRODUCTS AND TREATMENTS**

The FDA approved products and treatments available for your condition include [specify available treatments]. It is unlikely; however, that all currently approved and recognized usual treatments are likely to prolong your life.

**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**

Your eligibility for hospice care may be withdrawn once you begin the investigational treatment and that care may be reinstated if the treatment ends and you meet hospice eligibility requirements. In-home health care may also be denied if you begin investigational 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.

[Describes the potentially most serious outcomes of using the investigational drug or biologic and describe the most likely outcome. This description shall include the possibility that new, unanticipated, different, or more serious symptoms might result and that death could be hastened by the proposed treatment. The description should be based on the treating physician’s knowledge of the proposed treatment in conjunction with an awareness of the patient’s condition.]

**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/ biologics]* will help, there is no proof of this yet.

[List reasonably forseeable benefits of the drug or biologic. 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 biologic] will be provided free of charge to you.]

 *or*

[The cost of      is      .]

Your insurance plan, if any, and health care provider are not required to pay for treatment with this [drug or biologic] or any care or treatments consequent to use of the investigational drug or biologic. You are financially responsible for all expenses related to the use of the investigational drug or biologic, and this includes your estate.

**CONFIDENTIALITY**

All information about your treatment with [Name of drug or biologic] 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 biologic], 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. Records provided to authorized, non-UCI entities may contain identifiable information about you as permitted by law or with your written consent.

In addition, the Right to Try Act requires that a report be submitted, biannually, to the California Department of Public Health, Medical Board of CA and Osteopathic Board of CA. The reports will include the following information, which will not include information that directly identifies you:

(1) The number of requests made for an investigational drug, biological product, or device.

(2) The status of the requests made.

(3) The duration of the treatment.

(4) The costs of the treatment paid by eligible patients.

(5) The success or failure of the investigational drug, biological product, or device in treating the immediately life-threatening disease or condition from which the patient suffers.

(6) Any adverse event for each investigational drug, biological product, or device.

**NEW FINDINGS**

If, during the course of this investigational treatment with [Name of drug or biologic], 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 investigational 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 “Experimental Subject’s Bill of Rights” form. **Receipt of this investigational 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 investigational 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**

***REQUIRED FOR RTT***

**UNIVERSITY OF CALIFORNIA, IRVINE**

**Experimental Subject's Bill of Rights**

**The rights listed below are the right of every individual asked to participate in this experimental treatment. You have the right:**

1. To be told about the nature and purpose of the experimental treatment.
2. To be told about the procedures to be followed in the experimental treatment, and whether any of the drugs, biologics, 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 experimental treatment.
4. To be told of any benefits that you may reasonably expect from receiving the experimental treatment, if applicable.
5. To receive a description of any alternative procedures, drugs, biologics, or biologics that might be helpful, and their risks and benefits compared to the proposed experimental treatment.
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 experimental treatment both before agreeing to participate and at any time during the course of the treatment.
8. To refuse to receive the experimental treatment. Participation is voluntary. You may refuse or discontinue the experimental treatment 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 did not receive the experimental treatment.
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 experimental treatment without any force, coercion, or undue influence.

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If you have any concerns or questions regarding the experimental treatment, you should contact your primary physician listed at the top of the consent form.

1. NOTE: Use of an unapproved device not allowed under RTT. [Use the expanded access process](https://research.uci.edu/compliance/human-research-protections/researchers/expanded-access-and-right-to-try.html). [↑](#footnote-ref-1)