PI WORKSHEET: Right to Try

The purpose of this worksheet is to provide support for intended for treatment with an investigational drug or biologic under the provisions of Right to Try (RTT) and to provide support the Committee reviewing such uses. This worksheet is to be used when overseeing such uses. For more information visit: [Right to Try - Unapproved Drugs or Biologics](https://research.uci.edu/human-research-protections/clinical-research/drugs-and-biologics-used-in-clinical-research/right-to-try-drugs-biologics/).

Attach this protocol to the “Basic Study Information” section of the ZOT IRB application. Other supplemental documentation (i.e. consent, other) can be attached in “Local Site Documents”.

**1. Submission Information**

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| **Basic Information**  |  **Submission Details**  |
| **1.1 IRB Number:** | ​​ Click or tap here to enter text.  |
| **1.2 Short Title:** | ​​ Click or tap here to enter text.  |

1. Treating Physician Checklist

Confirm the following as part of preparing for Right to Try at UC Irvine:

**2.1 Drug Applicability Criteria:** (Check if “Yes.” All must be checked.)

[ ]  The investigational drug or biologic has successfully completed a Phase I clinical trial.

[ ]  The drug or biologic is under investigation in a clinical trial.

[ ]  The drug or biologic is actively being developed/produced by the manufacturer OR not placed on clinical hold.

**2.2 Patient Criteria:** (Check if “Yes.” All must be checked.)

[ ]  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).

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| Provide specific findings justifying this determination. Click or tap here to enter text. |

[ ]  The patient has exhausted all other approved treatment options currently approved by the Food and Drug Administration (FDA).

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| Describe why other FDA approved treatment options are not viable. Click or tap here to enter text. |

[ ]  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.

**2.3 Gather the Following Documents. Seek and Obtain IRB Approval:**

[ ]  Draft a consent document using HRP-498 - [CONSENT - Right to Try](HRP-506%20%E2%80%93%20CONSENT%20-%20Expanded%20Access).

[ ]  Review and sign Treating Physician Attestation. See section 6 of the form.

[ ]  Submit documentation to the IRB through the ZOT IRB application.

[ ]  Secure signature on the Consulting Physician Attestation before treatment begins. See section 7 of the form.

[ ]  Notify UCI Chief Medical Officer of RTT request.

**2.4 Other Treating Physician Responsibilities:**

[ ]  Consult with Clinical Trials Team in Sponsored Projects Administration to determine whether an agreement is necessary with the sponsor/manufacturer.

[ ]  All cancer-related patient care must undergo [Tumor Board](https://cancer.uci.edu/research/clinical-research/disease-oriented-teams) review. To submit a study for review, [download](https://cancer.uci.edu/sites/default/files/2021-02/dot-tb-feasibility-app-final-2021.pdf) the application. Email the completed application to CancerCenter\_Committees@hs.uci.edu

[ ]  Consult with Research Revenue Integrity (RRI) to determine billing implications.

[ ]  Register the patient in OnCore, as determined by RRI.

[ ]  Consult with Investigational Drug Services pharmacy to determine drug requirements.

[ ]  Ensure patient understands financial and health care considerations outlined in consent form.

[ ]  Treating physician will not be compensated directly by the manufacturer.

**2.5 Provide the Following Within 30 Days of Beginning of Treatment:**

[ ]  Provide the following to IRB@research.uci.edu. Indicate “Right to Try Follow Up” in the subject line. *Do not include patient identifiable information or Protected Health Information (PHI).*

[ ]  Provide a copy of the signed attestation.

[ ]  Provide the following status as required for UCI HRP reporting to the State Department of Public Health, the Medical Board of California, and the Osteopathic Medical Board of California:

[ ]  The duration of the treatment.

[ ]  The costs of the treatment paid by eligible patients.

[ ]  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.

[ ]  Any adverse event for each investigational drug, biological product, or device.

1. Treatment Plan

**3.1 Treatment Plan:** Specify the treatment plan including the dosage (as applicable) and duration of treatment. Do not include patient identifiable data nor protective health information (PHI).

[ ]  ***This is included in a separate treatment plan attached.***

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| Click or tap here to enter text. |

**3.2 Safety, Monitoring, and Data:** Describe provisions for safety, monitoring and collecting data.

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| Click or tap here to enter text. |

1. Consent Process

**4.1** **Consent criteria** (Check if “Yes”. All must be checked)

[ ]  Informed consent will be sought from the patient or the patient’s Legally Authorized Representative (LAR) when the patient lacks the capacity to consent, and attested to by the patient’s primary physician and the uninvolved consulting physician.

[ ]  If non-UCI covered components will access PHI, HIPAA Research Authorization will be obtained. Attach the HIPAA Form.

[ ]  If this study includes a non-English-speaking patient, the English version of the consent materials will be translated for non-English speaking participant or their LAR.

1. Financial Considerations for Patients

**5.1 Patient Cost:** State the cost of the treatment. In the case that the sponsor may cover costs, specify what the patient will be charged.

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| Click or tap here to enter text. |

1. Treating Physician Attestation

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. FDA for any use;
3. Has completed Phase 1 trials;
4. Remains under investigation by the FDA (i.e., an 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.
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 all applicable licensing organizations.
5. I will not be compensated directly by the manufacturer.
6. A Consulting Physician has completed the Consulting Physician Attestation Form.
7. Prior to providing treatment, I will confirm that the Patient:
8. 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.
9. 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)

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**Name of Treating Physician**

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**Signature of Treating Physician Date**

 7. Consulting Physician Attestation

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.
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 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)

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**Name of Consulting Physician**

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**Signature of Consulting Physician Date**