



Policy and Guidance: Right to Try

(updated February 26, 2021)

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Brief Background

In May 2018, the Federal Right to Try Act was signed into law, creating a federal framework for patients to access investigational new drugs outside of clinical trials and outside of the U.S. Food and Drug Administration’s (FDA) expanded access program. The federal law enables manufacturers and physicians to provide investigational drugs to eligible patients without risk of liability. It follows California’s passage of the State’s Right to Try Act, signed into law in 2016. Similar to the federal law, the California law enables manufacturers and physicians to provide investigational products to eligible patients without risk of liability under state law.

Federal Law versus California Law

Both the federal and state right to try laws enable patients meeting certain criteria under each law to receive access to investigational products without FDA oversight. However, the laws differ in fundamental ways that should be considered before providing an investigational product to a patient without FDA authorization.

Federal Law	California Law
Allows for the use of investigational drugs and biologics only	Allows for the use of investigational drugs, biologics, and devices
Patients must have a “life-threatening disease of condition”	Patients must have an “immediately life-threatening disease or condition”, defined as a stage of disease in which there is a reasonable likelihood death will occur in a matter of months.
Only the treating physician must document the use of the investigational product and attest that the patient meets the federal criteria’s	The treating physician and an uninvolved physician must document the recommendation of the investigational product and attest that the patient meets the state law criteria’s
There are no requirements to consent, apart from obtaining consent from the patient, and	The consent form given to patients must contain information from the California Health and Safety Code – Section 111548.1(h)(1)

<p>the law is exempt from 21 CFR Parts 50 and 56.</p> <ul style="list-style-type: none"> ➤ IRB review is not required. 	<p>and must meet the requirements set forth in the California Protection of Human Subjects in Medical Experimentation Act.</p> <ul style="list-style-type: none"> ➤ The IRB must review and approve the protocol and consent form. ➤ The CA Experimental Subject Bill of Rights must be provided to the patient/LAR.
<p>Financial Responsibility – Silent</p>	<p>Financial Responsibility – The consent form must clearly state the financial responsibility of the patient, health benefit plan and manufacturer with respect to treatment costs following use of the investigational product.</p>
<p>Manufacturer Responsibility – No obligation to make an investigational product available to a patient.</p>	<p>Manufacturer Responsibility – No obligation to make an investigational product available to a patient and the manufacturer may recover the costs of the product.</p>
<p>Disciplinary Action Against a Physician – No liability against a prescriber, dispenser, or other individual entity, unless the relevant conduct constitutes reckless or willful misconduct, gross negligence, or an intentional tort under any applicable State law.</p>	<p>Disciplinary Action Against a Physician - The Medical Board of California and the Osteopathic Medical Board of California are prohibited from taking any disciplinary action against a physician’s license to practice medicine based solely upon the physician’s recommendation to treat or treatment of a patient with an investigational product, so long as the protocol was approved by an IRB.</p> <ul style="list-style-type: none"> ➤ The Act also provides that any actions taken pursuant to the state law by a manufacturer or any other person or entity involved in caring for the patient cannot serve as the basis for any civil, criminal or disciplinary claim or cause of action under the state law.
<p>Reporting Requirement - The sponsor or manufacturer will make information available to the FDA, which will then be publicly posted</p>	<p>Reporting Requirement - The IRB must report biannually information regarding the number of requests made to the IRB for an investigational product, the status of each request, the duration of treatment, the costs of treatment paid by patients, the success or failure of the investigational product in treatment, and adverse events.</p>

UCLA OHRPP will abide by:

- The stricter California Right to Try law requirements
- IRB review and approval is required for all Right to Try uses at UCLA
- The federal law which does not allow the use of investigational devices
 - If the treating physician wish to use a device, the expanded access process should be used instead.

Treating Physician Responsibilities

Treating physicians must comply with the following:

- Seek permission from the product manufacturer to provide the investigational drugs or biologics. Note, there is no law that requires a manufacturer to make its product available outside of clinical trials.
- Provide the proposed treatment plan, including provisions for safety, monitoring, and collecting data
- Indicate the duration of treatment
- Obtain a concurrence in writing from an uninvolved physician with the use of the test article ([see Appendix II](#))
- Attest that the patient has an “Immediately life-threatening disease or condition” meaning a stage of disease in which there is a reasonable likelihood that death will occur within a matter of months
- Attest that the patient has not been accepted to participate in the nearest clinical trial to their 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.
- The “Investigational drug or biological product” is a drug or biological product that has successfully completed phase one of a clinical trial approved by the United States Food and Drug Administration, but has not been approved for general use by the United States Food and Drug Administration and remains under investigation in a clinical trial approved by the United States Food and Drug Administration.
- Obtain written informed consent from the eligible patient, or their legally authorized representative when the patient lacks the capacity to consent, and attested to by the patient’s primary physician and a witness.
- Attest that all other FDA approved treatment options have been exhausted/considered
- The treating physician is in good standing with the physician’s licensing organization or board
- The treating physician will not be compensated directly by the manufacturer
- Ensure patient understands financial and health care considerations outlined in consent form
- Complete the reporting requirement of success and failure. The treating physician will receive a notification from BruinIRB after 30 days from approval requesting this reporting requirement be reported through a PAR.

Other Local Responsibilities:

- Consult with Clinical Trials Team in Sponsored Projects Administration to determine whether an agreement is necessary with the sponsor/manufacturer.
 - In order to execute an agreement for a Right to Try product please contact the - CTC&SR department at clinicaltrials@mednet.ucla.edu.
- Consult with CTSI Clinical Research Finance to determine billing implications
- Consult with Investigational Drug Services pharmacy to determine drug requirements
- Register the patient in OnCore, as determined by CTSI

Treating physicians should not confuse Right to Try with the FDA’s Expanded Access program. See UCLA OHRPP Guidance and Procedures: [Use of Drugs and Biologics in Clinical Research and Treatment](#) or [Use of Devices in Clinical Research and Treatment](#).

IRB Responsibilities

The UCLA OHRPP will evaluate the following for each Right to Try application received:

- The proposed treatment plan is for the use of a drug or biological product that has successfully completed phase one of a clinical trial approved by the United States Food and Drug Administration, but has not been approved for general use by the United States Food and Drug Administration and remains under investigation in a clinical trial approved by the United States Food and Drug Administration.
- The treating physician's treatment plan makes adequate provisions for ensuring the safety of the patient, including monitoring (e.g. types of tests/exams, etc.) and appropriate plans for collecting reporting data
- The treating physician has attested that the patient meets the eligibility criteria
- The treating physician has attested that a consulting physician has concurred in writing with the use of the test article for the patient
- Ensure that the treating physician will follow standard medical practice to protect the privacy interests of the patient
- Review of the written informed consent to ensure it is consistent with the informed consent requirements of the [Protection of Human Subjects in Medical Experimentation Act](#)

Upon each Right to Try application received, the appropriate MIRB chair/designee will review the submission and provide chair/designee concurrence and/or reviewed by the full board.

Consent Form Requirements

The UCLA OHRPP has created a consent form [template for Right to Try](#).

The UCLA consent form must contain the following information:

- The patient, or when the patient lacks the capacity to consent their legally authorized representative (LAR), must attest that they concur with the treating physician in believing that all currently approved and conventionally recognized treatments are unlikely to prolong the patient's life.
- Clearly identifies the specific proposed investigational drug or biological product that the patient is seeking to use.
- Describes the potentially best and worst outcomes of using the investigational drug or biological product and describes the most likely outcome. This description shall include the possibility that new, unanticipated, different, or worse symptoms might result, and that death could be hastened by the proposed treatment. The description shall be based on the treating physician's knowledge of the proposed treatment in conjunction with an awareness of the patient's condition.
- Clearly states that the patient's health benefit plan, if any, and health care provider are not obligated to pay for the investigational drug or biological product or any care or treatments consequent to use of the investigational drug or biological product.
- States that the patient understands that he or she is liable for all expenses consequent to the use of the investigational drug or biological product and that this liability extends to the patient's estate, except as otherwise provided in the patient's health benefit plan or a contract between the patient and the manufacturer of the drug or biological product.
- Clearly states that the patient's eligibility for hospice care may be withdrawn if the patient begins curative treatment and that care may be reinstated if the curative treatment ends and the patient meets hospice eligibility requirements.
- Clearly states that in-home health care may be denied if treatment begins.

A copy of the [California Experimental Subjects Bill of Rights](#) must be provided to the patient, or their LAR. However, patients, or their LAR, are not required to sign the UCLA research HIPAA

form, unless non-covered components of UC will have access to Protected Health Information (PHI). Questions regarding non-covered components of UC and access to PHI should be directed to [UCLA Office of Compliance Services](#).

BruinIRB Requirements

All treating physicians wishing to administer a treatment through the Right to Try mechanism, must submit a [BruinIRB](#) application for review and approval **prior** to administering any treatment.

BruinIRB Protocol Requirements:

The BruinIRB application system requires a protocol upload. For all Right to Try applications, the treating physician should create a protocol that contains the following information:

- Describe why other FDA approved treatment options are not viable,
- The proposed treatment plan,
- Provisions for safety, monitoring, and data collection,
- The cost of treatment, and
- Duration of treatment

See OHRPP [Right to Try protocol template](#).

Once approved, any modifications needed to the treatment plan, cost information, or any other changes must be reported in BruinIRB as a modification. IRB approval must be obtained prior to changing the patient's treatment plan or to edit the consent form.

Post-Approval Requirements (PAR) is required for all adverse events and the reporting requirement of the success or failure of the treatment plan.

The Right to Try applications will not require a continuing review and will not have an expiration date. However, the PI will be required to complete the annual PI assurance, the reporting requirement of the success or failure of the treatment plan and complete the closure of the BruinIRB submission.

References and Regulations

- Federal [Right to Try Act](#)
- California State [Right to Try Act](#)
- FDA Investigational New Drug Application [21 CFR 312.21](#)
- FDA Drugs Intended to Treat Life-threatening and Severely-debilitating Illnesses [21 CFR 312.81](#)
- California Health and Safety Provisions - [Protection of Human Subjects in Medical Experimentation Act](#)
- California Health & Safety Code – Investigational drugs, biological products, and devices [§111548.1\(d\)](#)
- Reagan-Udall Foundation for the Food and Drug Administration – [Expanded Access Pathway](#)
- Clinical Research Pathways [Right to Try Guide for IRBs](#)

Change history:

2/26/2021: Added information re: BruinIRB and Appendix I & II.

Appendix I – Treating Physician Attestation

Confirm the following information and provide your signature below.

As I the Treating Physician, I have:

1. Confirmed that the investigational drug or biologic:
 - a. Has not yet approved by the FDA for any use;
 - b. Has completed Phase 1 trials;
 - c. Remains under investigation by the FDA (i.e., a NDA or BLA has been filed with the FDA, or under investigation in a clinical trial; and is
 - d. Actively being developed/produced by manufacturer or not placed on clinical hold.
2. Examined the patient and his/her relevant medical records and determined the 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:

 - a. Has an immediately life-threatening disease or condition defined as 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\(d\)](#)).
 - b. Has considered all other treatment options currently approved by the United States Food and Drug Administration (FDA).
 - c. 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. I acknowledge that I am in good standing with the all applicable licensing organizations.
5. A Consulting Physician will confirm the diagnosis and prognosis.
6. Prior to providing treatment, I will confirm that the eligible patient:
 - a. Has given written informed consent for the use of the investigational drug or biologic; 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 UCLA IRB.
 - b. 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\(b\)](#).

Name of Primary Physician

Signature of Treating Physician

Date

Appendix II – Uninvolved 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 and has made an informed decision.

“Eligible patient” is a person who meets all of the following conditions:

- a. Has an immediately life-threatening disease or condition defined as 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\(d\)](#)).
 - b. Has considered all other treatment options currently approved by the United States Food and Drug Administration (FDA).
 - c. 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.
 - d. Has received a recommendation from his or her primary physician for the use of investigational drug or biological product.
4. Prior to providing treatment, I will confirm that the eligible patient:
 - a. 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 UCLA IRB.
 - b. Has received documentation from his/her primary physician attesting that the patient meets the requirements of [California Health and Safety Code Article 4.5 Right to Try Act 111548.1\(b\)](#).

Name of Consulting Physician

Signature of Consulting Physician

Date