Information needed for Chair/Designee or Board to assess requested use:		
☐		Proposed treatment plan for use of drug or biological product.[1]
☐		Assurances that attestation that patient meets the eligibility requirements from treating physician and consulting physician have been obtained.
☐		Draft Consent Document using the UCLA Right to Try Template.
☐		Provides Assurance that the intended drug has completed an FDA-Regulated Phase 1 trial and remains under active investigation by the FDA.
Eligible patient meets the following Criteria under CA Health and Safety Code Section 1 Article 4.5 111548.1(b):		
☐		The patient has an immediately life-threatening condition[2].
☐		Has considered/exhausted all other treatment options currently approved by the FDA.
☐		Has not been accepted to participate in the nearest clinical trial to his or 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.
Consent Form meets the following requirements under CA Health and Safety Code Section 1 Article 4.5 111548.1(h):		
☐		Attests to the fact that the patient, or when the patient lacks the capacity to consent his or her legally authorized representative, concurs with the patient's 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.
☐		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.
☐		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.

[1] Although CA State Right to Try Law allows for use of devices, the Federal Right to Try Act does not permit use of medical devices.

[2] "Immediately life-threatening disease or condition" means a stage of disease in which there is a reasonable likelihood that death will occur within a matter of months.

☐		Written, informed consent for purposes of this article shall be consistent with the informed consent requirements of the Protection of Human Subjects in Medical Experimentation Act (Chapter 1.3 (commencing with Section 24170) of Division 20).
		Reviewer Considerations:
☐		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[3].
☐		Treating Physician will follow standard medical practice to protect the privacy interests of the patient.
☐		Additional safeguards are included in the treatment plan where the therapy may require special monitoring or other safeguards.

[3] Federal law requires that the sponsor or manufacturer make information available to the FDA (which the FDA must publicly post), the California law imposes an obligation upon the physician's IRB (or an accredited IRB) to biannually report 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.