

ORDINANCE NO. _____

AN ORDINANCE OF THE CITY COUNCIL OF THE CITY OF LANCASTER, CALIFORNIA, ADDING CHAPTER 8.80 TO THE LANCASTER MUNICIPAL CODE ESTABLISHING THE RIGHT TO TRY INVESTIGATIONAL THERAPIES FOR ALL PERSONS AGED 70 OR OLDER, RESTRICTED TO LICENSED MEDICAL FACILITIES WITHIN THE CITY

WHEREAS, the City of Lancaster is a charter city under Article XI, Section 5 of the California Constitution and may enact ordinances concerning its municipal affairs;

WHEREAS, California Health & Safety Code § 111548 et seq. provides for “qualified patients” to access investigational therapies after completion of Phase I trials;

WHEREAS, the City Council finds that individuals aged 70 or older facing conditions without satisfactory FDA-approved treatments should have access to investigational therapies, subject to strict oversight;

WHEREAS, the City Council finds that restricting administration to licensed medical facilities within Lancaster ensures appropriate oversight and patient safety;

WHEREAS, this ordinance is intended to grant rights and immunities at least equivalent to those provided by state law and not to conflict with California Health & Safety Code § 111548 et seq.;

NOW, THEREFORE, THE CITY COUNCIL OF THE CITY OF LANCASTER, CALIFORNIA, DOES HEREBY ORDAIN AS FOLLOWS:

Section 1. The City Council of the City of Lancaster hereby finds and determines that the above recitals are true and correct.

Section 2. Chapter 8.80 is hereby added to the Lancaster Municipal Code to read as set forth in Exhibit “A” attached hereto.

Section 3. If any section, subsection, sentence, clause, phrase or portion of this Ordinance is held for any reason to be invalid or unconstitutional by the decision of any court of competent jurisdiction, such decision shall not affect the validity of the remaining portions of this Ordinance. The City Council of the City of Lancaster hereby declares that it would have adopted this Ordinance and each section, subsection, sentence, clause, phrase or portion thereof, irrespective of the fact that any one or more sections, subsections, sentences, clauses, phrases or portions be declared invalid or unconstitutional.

Section 4. The Mayor shall sign and the City Clerk shall certify to the passage and adoption of this Ordinance and shall cause the same to be published and posted pursuant to the provisions of law in that regard and this Ordinance shall take effect 30 days after adoption.

I, Andrea Alexander, City Clerk of the City of Lancaster, do hereby certify that the foregoing ordinance was regularly introduced and placed upon its first reading on the _____ day of

_____, 2025, and placed upon its second reading and adoption at a regular meeting of the City Council on the ____ day of _____, 2025, by the following vote:

AYES:

NOES:

ABSTAIN:

ABSENT:

ATTEST:

APPROVED:

ANDREA ALEXANDER
City Clerk
City of Lancaster

R. REX PARRIS
Mayor
City of Lancaster

STATE OF CALIFORNIA)
COUNTY OF LOS ANGELES) ss
CITY OF LANCASTER)

CERTIFICATION OF ORDINANCE
CITY COUNCIL

I, _____, _____ City of Lancaster, California, do hereby certify that this is a true and correct copy of the original Ordinance No. , for which the original is on file in my office.

WITNESS MY HAND AND THE SEAL OF THE CITY OF LANCASTER, on this _____ day of _____, _____.

(seal)

EXHIBIT “A”

CHAPTER 8.80

AGE BASED RIGHT TO TRY ORDINANCE

Sections:

8.80.010	Title.
8.80.020	Definitions.
8.80.030	Eligibility and Enrollment.
8.80.040	Procedural Requirements.
8.80.050	Prohibition on Interference.
8.80.060	Immunity from Liability.
8.80.070	Preemption and Construction.

8.80.010 Title.

This chapter shall be known and may be cited as the “City of Lancaster Age Based Right to Try Ordinance.”

8.80.020 Definitions.

For purposes of this chapter, the following definitions apply:

“City.” The City of Lancaster, California.

“Eligible Individual.” An individual who meets at least one of the following criteria: (i) has a serious life-threatening illness, defined as a disease or condition that, without life-sustaining procedures, will result in death or permanent unconsciousness, as certified by a licensed physician, has considered all FDA-approved treatment options, is unable to participate in a clinical trial within 50 miles of their home, and has provided written Informed Consent; and (ii) is 70 years of age or older, has decision making capacity as certified by a licensed physician, has a condition for which FDA-approved treatments are deemed insufficient by a licensed physician, and has provided written Informed Consent.

“FDA” means the United States Food and Drug Administration.

“Informed Consent” means written informed consent meeting the standards set forth in Health & Safety Code section 111548.1(h)(1).

“Investigational Therapy” means a drug, biological product, or device for which the sponsor has filed an Investigational New Drug (IND) or Investigational Device Exemption (IDE) application with the FDA and has completed a Phase I clinical trial approved by the FDA.

“Licensed Medical Facility” means any hospital, clinic, or health care facility located within the City of Lancaster that holds a valid California license to administer prescription drugs or biological products.

“Physician” means a person licensed to practice medicine in the State of California and in good standing under California law.

“Manufacturer” means an entity that produces or prepares an Investigational Therapy.

8.80.030 Eligibility and Enrollment.

An Eligible Individual may enroll in an Investigational Therapy at a Licensed Medical Facility only if:

- A. The individual is aged 70 or older.
- B. A Physician certifies in writing that the individual has decision making capacity and voluntarily elects to pursue an Investigational Therapy.
- C. The individual executes an informed consent document compliant with California Health & Safety Code § 111548 et seq.
- D. All administration, monitoring, and follow up occur at a Licensed Medical Facility within the City of Lancaster.

8.80.040 Procedural Requirements.

- A. Physician Responsibilities. The attending Physician must:
 - 1. Obtain the Eligible Individual's Informed Consent on a form that clearly explains known and potential risks, benefits, and alternatives; and
 - 2. Provide a statement that the therapy is investigational and that its safety and efficacy are not yet fully established; and
 - 3. Provide written certification of patient eligibility;
 - 4. Ensure all treatment is conducted at a Licensed Medical Facility.
- B. Manufacturer Responsibilities. The Manufacturer shall provide the attending Physician at the Licensed Medical Facility with:
 - 1. Documentation of Phase I trial completion;
 - 2. Known safety and risk information; and
 - 3. A declaration of compliance with all applicable federal requirements.
- C. Record Keeping. The Physician, Manufacturer, and Licensed Medical Facility shall each preserve all certifications, consents, and administration records for at least seven years and make them available for inspection by the City upon request.

8.80.050 Prohibition on Interference.

No official, employee, or agent of the City of Lancaster—shall prohibit, penalize, interfere with, or otherwise restrict an Eligible Individual's access to an Investigational Therapy under this Chapter, provided all requirements of this Chapter are met.

8.80.060 Immunity from Liability.

This Chapter does not create a private cause of action, and actions taken pursuant to this Chapter shall not serve as a basis for a civil, criminal, or disciplinary claim or cause of action, including, but not limited to, product liability, medical negligence, or wrongful death, against a manufacturer of an investigational drug, biological product, or device, or against any other person or entity involved in the care of an eligible patient for harm done to the eligible patient or his or her heirs resulting from the investigational drug, biological product, or device, or the use

or nonuse thereof, if the manufacturer or other person or entity has complied with the terms of this article in relation to the eligible patient, unless there was willful misconduct or gross negligence.

8.80.070 Preemption and Construction.

- A. To the extent any provision of this Chapter conflicts with California Health & Safety Code § 111548 et seq., the state statute shall prevail; this Chapter shall be construed to afford rights and immunities at least equal to those provided by state law.
- B. Nothing herein is intended to expand or diminish any right conferred by state or federal law beyond what is expressly authorized by California Health & Safety Code § 111548 et seq.