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## **HEALTH AND SAFETY CODE - HSC**

DIVISION 104. ENVIRONMENTAL HEALTH [106500 - 119406] ( Division 104 added by Stats. 1995, Ch. 415, Sec. 6. ) PART 5. SHERMAN FOOD, DRUG, AND COSMETIC LAWS [109875 - 111929.4] ( Part 5 added by Stats. 1995, Ch. 415, Sec. 6.)

CHAPTER 6. Drugs and Devices [111225 - 111656.13] (Chapter 6 added by Stats. 1995, Ch. 415, Sec. 6.)

ARTICLE 4. Experimental Use of Drugs [111515 - 111545] (Article 4 added by Stats. 1995, Ch. 415, Sec. 6.)

**111515.** As used in this article, "experimental drug" means any of the following:

A drug intended for investigational use under Section 111595.

(Added by Stats. 1995, Ch. 415, Sec. 6. Effective January 1, 1996.)

111520. No person shall prescribe or knowingly administer an experimental drug to another person in violation of this article.

(Added by Stats. 1995, Ch. 415, Sec. 6. Effective January 1, 1996.)

111525. Prior to prescribing or administering an experimental drug, consent to the use of the drug shall be obtained in the method and manner specified in Chapter 1.3 (commencing with Section 24170) of Division 20.

(Added by Stats. 1995, Ch. 415, Sec. 6. Effective January 1, 1996.)

111530. (a) Notwithstanding the provisions of Section 24175, if the subject is a minor, consent shall be provided by a parent or guardian of the subject and shall also be provided by the subject if the subject is seven years of age or older.

(b) Consent given pursuant to this section shall only be for the prescribing or administering of an experimental drug that is related to maintaining or improving the health of the subject or related to obtaining information about a pathological condition of the subject.

(Added by Stats. 1995, Ch. 415, Sec. 6. Effective January 1, 1996.)

111535. Consent given pursuant to Section 111525 may be revoked at any time by either verbal or written communication to the practitioner supervising the administration of the experimental drug.

(Added by Stats. 1995, Ch. 415, Sec. 6. Effective January 1, 1996.)

111540. Prior to administering an experimental drug, the experimental activity as a whole, including the consent procedures required by Section 111525, shall be reviewed and approved by a committee for the protection of human subjects that is acceptable, as determined by the department. A committee for the protection of human subjects that operates under a general or special assurance approved by the federal Department of Health, Education, and Welfare pursuant to Part 46 of Title 45 of the Code of Federal Regulations shall be an acceptable committee for purposes of this section. A copy of the consent procedures approved by a committee for the protection of human subjects shall be filed with the department prior to the commencement of the experiment.

(Added by Stats. 1995, Ch. 415, Sec. 6. Effective January 1, 1996.)

111545. A person having an ownership interest in a skilled nursing facility or intermediate care facility, as those terms are defined in Section 1250, may not prescribe an experimental drug for a patient in the facility.

(Added by Stats. 1995, Ch. 415, Sec. 6. Effective January 1, 1996.)