



Home	Bill Information	California Law	Publications	Other Resources	My Subscriptions	My Favorites
------	------------------	----------------	--------------	-----------------	------------------	--------------

Code: Section:

[Up^](#) [Add To My Favorites](#)

HEALTH AND SAFETY CODE - HSC

DIVISION 105. COMMUNICABLE DISEASE PREVENTION AND CONTROL [120100 - 122476] (*Division 105 added by Stats. 1995, Ch. 415, Sec. 7.*)

PART 4. HUMAN IMMUNODEFICIENCY VIRUS (HIV) [120775 - 121349.3] (*Part 4 added by Stats. 1995, Ch. 415, Sec. 7.*)

CHAPTER 10. Acquired Immune Deficiency Syndrome (AIDS) Research Confidentiality Act [121075 - 121125] (*Chapter 10 added by Stats. 1995, Ch. 415, Sec. 7.*)

121075. Research records, in a personally identifying form, developed or acquired by any person in the course of conducting research or a research study relating to HIV or AIDS shall be confidential, and these confidential research records shall not be disclosed by any person in possession of the research record, nor shall these confidential research records be discoverable, nor shall any person be compelled to produce any confidential research record, except as provided by this chapter.

(*Amended by Stats. 2006, Ch. 20, Sec. 9. Effective April 17, 2006.*)

121080. Confidential research records may be disclosed in accordance with the prior written consent of the research subject with respect to whom the research record is maintained, but only to the extent, under the circumstances, to the persons, and for the purposes the written consent authorizes. Any disclosure authorized by a research subject shall be accompanied by a written statement containing substantially the same language as follows:

"This information has been disclosed to you from a confidential research record the confidentiality of which is protected by state law and any further disclosure of it without specific prior written consent of the person to whom it pertains is prohibited. Violation of these confidentiality guarantees may subject you to civil or criminal liabilities."

(*Added by Stats. 1995, Ch. 415, Sec. 7. Effective January 1, 1996.*)

121085. (a) Confidential research records shall be protected in the course of conducting financial audits or program evaluations, and audit personnel shall not directly or indirectly identify any individual research subject in any report of a financial audit or program evaluation. To the extent it is necessary for audit personnel to know the identity of individual research subjects, authorized disclosure of confidential research records shall be made on a case-by-case basis, and every prudent effort shall be exercised to safeguard the confidentiality of these research records in accordance with this chapter. Information disclosed for audit or evaluation purposes should be used only for audit and evaluation purposes and may not be redisclosed or used in any other way.

(b) Nothing in this section imposes liability or criminal sanction for disclosure of confidential research records in accordance with any reporting requirement for a case of HIV, including AIDS, by the department or the Centers for Disease Control and Prevention under the United States Public Health Services.

(*Amended by Stats. 2006, Ch. 20, Sec. 10. Effective April 17, 2006.*)

121090. Notwithstanding Section 121080, whether or not the research subject, with respect to whom any confidential research record is maintained, gives prior written consent, the content of the confidential research record may be disclosed in any of the following situations:

(a) To medical personnel to the extent it is necessary to meet a bona fide medical emergency of a research subject.

(b) To the department to the extent necessary for the conduct of a special investigation pursuant to Section 100325, in which case the confidentiality provisions of Chapter 8 (commencing with Section 121025) shall apply.

(*Added by Stats. 1995, Ch. 415, Sec. 7. Effective January 1, 1996.*)

121095. The content of any confidential research record shall be disclosed to the research subject, the legal representative of the research subject if the research subject is a minor, or the personal representative of a deceased research subject to whom the

record pertains, thirty (30) days after written request therefor by the research subject, the legal representative or the personal representative.

(Added by Stats. 1995, Ch. 415, Sec. 7. Effective January 1, 1996.)

121100. (a) No confidential research record may be compelled to be produced in any state, county, city or other proceeding in order to initiate or substantiate any criminal charge or charges against a research subject, or to conduct an investigation of a research subject, unless a court finds there is reasonable likelihood that the records in question will disclose material information or evidence of substantial value in connection with the criminal charge or charges or investigation, and there is no other practicable way of obtaining the information or evidence.

In addition, no confidential research record shall be disclosed, discoverable, or compelled to be produced in order to initiate or substantiate any criminal charge or charges against a research subject until after a showing of good cause. In assessing good cause, the court shall weigh the public interest and need for disclosure against the injury to the research subject and the harm to the research being undertaken. Upon the granting of an order to produce, the court, in determining the extent to which disclosure of all or any part of a confidential research record is necessary, shall impose appropriate safeguards against unauthorized disclosure, that shall include, but not necessarily be limited to, the individuals or bodies that may have access to the data, the purposes for which the data shall be used, prohibitions on further disclosure and protection of the identities of other research subjects.

(b) No confidential research record may be compelled to be produced in any state, county, city or other civil proceeding, except as expressly provided in this chapter.

(Added by Stats. 1995, Ch. 415, Sec. 7. Effective January 1, 1996.)

121105. Prior to participation of an individual in a research study relating to HIV or AIDS, both of the following requirements shall be met:

(a) The informed consent of each research subject shall be obtained in the method and manner required by Section 46.116, (a) and (b), of Part 46 of Title 45 of the Code of Federal Regulations and be documented in accordance with Section 46.117 of that part.

(b) Each research subject shall be provided with an explanation in writing, in language understandable to the research subject, of the rights and responsibilities of researchers and research subjects under this chapter.

(Amended by Stats. 2006, Ch. 20, Sec. 11. Effective April 17, 2006.)

121110. (a) Any person who negligently discloses the content of any confidential research record, as defined in subdivision (c) of Section 121125, to any third party, except pursuant to this chapter, shall be assessed a civil penalty in an amount not to exceed two thousand five hundred dollars (\$2,500), plus court costs, as determined by the court, which penalty and costs shall be paid to the subject of the test.

(b) Any person who willfully or maliciously discloses the content of any confidential research record, as defined in subdivision (c) of Section 121125, to any third party, except pursuant to this chapter, shall be assessed a civil penalty in an amount not less than five thousand dollars (\$5,000) and not more than ten thousand dollars (\$10,000), plus court costs, as determined by the court, which penalty and costs shall be paid to the subject of the test.

(c) Any person who willfully, maliciously, or negligently discloses the content of any confidential research record, as defined in subdivision (c) of Section 121125, to a third party, except pursuant to this chapter, that results in economic, bodily, or psychological harm to the research subject, is guilty of a misdemeanor, punishable by imprisonment in the county jail for a period not to exceed one year, or a fine of not to exceed twenty-five thousand dollars (\$25,000), or both.

(d) Any person who commits any act described in subdivision (a) or (b) shall be liable to the subject for all actual damages for economic, bodily, or psychological harm that is a proximate result of the act.

(e) Any person who negligently or willfully violates Section 121105 is guilty of an infraction punishable by a fine of twenty-five dollars (\$25).

(f) Each violation of this chapter is a separate and actionable offense.

(g) Nothing in this section limits or expands the right of an injured research subject to recover damages under any other applicable law.

(Amended by Stats. 2006, Ch. 20, Sec. 12. Effective April 17, 2006.)

121115. In the event that the participation of an individual in a research study is disclosed, the information shall not be used to determine the employability or insurability of the research subject.

(Added by Stats. 1995, Ch. 415, Sec. 7. Effective January 1, 1996.)

121120. Nothing in this chapter shall preclude disclosure of information in order to further research efforts, including, but not limited to, the publication, dissemination, or sharing of raw data, statistics, or case studies, so long as no confidential research records concerning any research subject are disclosed.

(Added by Stats. 1995, Ch. 415, Sec. 7. Effective January 1, 1996.)

121125. For purposes of this chapter:

(a) "AIDS" means acquired immunodeficiency syndrome.

(b) "Disclosed" means to disclose, release, transfer, disseminate, or otherwise communicate all or any part of any confidential research record orally, in writing, or by electronic means to any person or entity, or to provide the means for obtaining the records.

(c) "Confidential research record or records" means any data or information in a personally identifying form, including name, social security number, address, employer, or other information that could, directly or indirectly, in part or in sum, lead to the identification of the individual research subject, developed or acquired by any person in the course of conducting research or a research study relating to HIV or AIDS.

(d) "HIV" means human immunodeficiency virus.

(Amended by Stats. 2006, Ch. 20, Sec. 13. Effective April 17, 2006.)