

- 3501.** The Legislature affirms the fundamental right of competent adults to make decisions about their participation in behavioral research.
- 3502.** Except as provided in Section 1706 of the Welfare and Institutions Code, no biomedical research shall be conducted on any prisoner in this state.
- 3502.5.** (a) Notwithstanding Section 3502, any physician who provides medical care to prisoners may provide a patient who is a prisoner with a drug or treatment available only through a treatment protocol or treatment IND (investigational new drug), as defined in Section 312 of Title 21 of the Code of Federal Regulations, if the physician determines that access to that drug is in the best medical interest of the patient, and the patient has given informed consent under Section 3521. (b) Notwithstanding any other provision of law, neither a public entity nor a public employee shall be liable for any injury caused by the administration of a drug pursuant to subdivision (a), where the administration is made in accordance with a treatment IND or a treatment protocol as defined in Section 312 of Title 21 of the Code of Federal Regulations.
- 3504.** Any physical or mental injury of a prisoner resulting from the participation in behavioral research, irrespective of causation of such injury, shall be treated promptly and on a continuing basis until the injury is cured.
- 3505.** Behavioral research shall be limited to studies of the possible causes, effects and processes of incarceration and studies of prisons as institutional structures or of prisoners as incarcerated persons which present minimal or no risk and no more than mere inconvenience to the subjects of the research. Informed consent shall not be required for participation in behavioral research when the department determines that it would be unnecessary or significantly inhibit the conduct of such research. In the absence of such determination, informed consent shall be required for participation in behavioral research.
- 3508.** Behavioral modification techniques shall be used only if such techniques are medically and socially acceptable means by which to modify behavior and if such techniques do not inflict permanent physical or psychological injury.
- 3509.5.** Nothing in this title is intended to diminish the authority of any official or agency to adopt and enforce rules pertaining to prisoners, so long as such rules are not inconsistent with this title.
- 3515.** The duties of the department are to determine:
- (a) That the risks to the prisoners consenting to research are outweighed by the sum of benefits to the prisoners and the importance of the knowledge to be gained.
 - (b) That the rights and welfare of the prisoners are adequately protected, including the security of any confidential personal information.
 - (c) That the procedures for selection of prisoners are equitable and that subjects are not unjustly deprived of the opportunity to participate.
 - (d) That adequate provisions have been made for compensating research related injury.
 - (e) That the rate of remuneration is comparable to that received by nonprisoner volunteers in similar research.
 - (f) That the conduct of the activity will be reviewed at timely intervals.
 - (g) That legally effective informed consent will be obtained by adequate and appropriate methods.

- 3516.** No behavioral research shall be conducted on any prisoner in this state in the absence of a determination by the department consistent with this title.
- 3517.** The department shall promulgate rules and regulations reasonably necessary for the effective administration of the provisions of this title. Action on proposals submitted shall be taken within 60 days. The regulations shall be submitted to the Joint Legislative Prison Committee for review and shall not become operative until 60 days after submission.
- 3518.** The department shall promulgate rules and regulations prescribing procedures to be followed by any person who has a grievance concerning the operation of any particular research program conducted pursuant to this title.
- 3519.** The department shall evaluate the impact of research on human subjects approved and conducted pursuant to this title, including any adverse reactions.
- 3520.** The department shall make a report due on or before January 1 of each odd-numbered year containing a review of each research program which has been approved and conducted. The report shall be transmitted to the Legislature and shall be made available to the public.
- 3521.** For the purposes of this title, a prisoner shall be deemed to have given his informed consent only if each of the following conditions are satisfied:
- (a) Consent is given without duress, coercion, fraud, or undue influence.
 - (b) The prisoner is informed in writing of the potential risks or benefits, or both, of the proposed research.
 - (c) The prisoner is informed orally and in writing in the language in which the subject is fluent of each of the following:
 - (1) An explanation of the biomedical or behavioral research procedures to be followed and their purposes, including identification of any procedures which are experimental.
 - (2) A description of all known attendant discomfort and risks reasonably to be expected.
 - (3) A disclosure of any appropriate alternative biomedical or behavioral research procedures that might be advantageous for the subject.
 - (4) The nature of the information sought to be gained by the experiment.
 - (5) The expected recovery time of the subject after completion of the experiment.
 - (6) An offer to answer any inquiries concerning the applicable biomedical or behavioral research procedures.
 - (7) An instruction that the person is free to withdraw his consent and to discontinue participation in the research at any time without prejudice to the subject.
- 3522.** At the time of furnishing a prisoner the writing required by subdivision (b) of Section 3521, the prisoner shall also be given information as to (a) the amount of remuneration the prisoner will receive for the research and (b) the manner in which the prisoner may obtain prompt treatment for any research-related injuries. Such information shall be provided in writing on a form to be retained by the prisoner.
- 3523.** The amount of such remuneration shall be comparable to that which is paid to nonprisoner volunteers in similar research.