

Introduced by Senator Pan

February 18, 2016

An act to amend Sections 3500 and 3502 of the Penal Code, relating to prisons.

LEGISLATIVE COUNSEL'S DIGEST

SB 1238, as amended, Pan. Inmates: biomedical data.

Existing law prohibits biomedical research, as defined, from being conducted on any prisoner in the state.

This bill would specify that biomedical research does not include the accumulation of statistical data in the assessment of the effectiveness of nonexperimental public health programs or treatment programs in which inmates routinely participate. The bill would authorize records-based biomedical research involving inmates that uses existing information, but which does not include prospective interaction with human subjects.

Vote: majority. Appropriation: no. Fiscal committee: yes.
State-mandated local program: no.

The people of the State of California do enact as follows:

- 1 SECTION 1. Section 3500 of the Penal Code is amended to
- 2 read:
- 3 3500. For purposes of this title:
- 4 (a) "Behavioral research" means studies involving, but not
- 5 limited to, the investigation of human behavior, emotion,
- 6 adaptation, conditioning, and response in a program designed to

1 test certain hypotheses through the collection of objective data.
2 Behavioral research does not include the accumulation of statistical
3 data in the assessment of the effectiveness of programs to which
4 inmates are routinely assigned, including, but not limited to,
5 education, vocational training, productive work, counseling,
6 recognized therapies, and programs that are not experimental in
7 nature.

8 (b) “Biomedical research” means research relating to or
9 involving biological, medical, or physical science. Biomedical
10 research does not include the accumulation of statistical data in
11 the assessment of the effectiveness of nonexperimental public
12 health programs or treatment programs in which inmates routinely
13 participate.

14 (c) “Psychotropic drug” means a drug that has the capability of
15 changing or controlling mental functioning or behavior through
16 direct pharmacological action. These drugs include, but are not
17 limited to, antipsychotic, antianxiety, sedative, antidepressant, and
18 stimulant drugs. Psychotropic drugs also include mind-altering
19 and behavior-altering drugs that, in specified dosages, are used to
20 alleviate certain physical disorders, and drugs that are ordinarily
21 used to alleviate certain physical disorders but may, in specified
22 dosages, have mind-altering or behavior-altering effects.

23 (d) “Research” means a class of activities designed to develop
24 or contribute to generalizable knowledge, including theories,
25 principles, or relationships, or the accumulation of data on which
26 they may be based, that can be corroborated by accepted scientific
27 observation and inferences.

28 (e) “Research protocol” means a formal document setting forth
29 the explicit objectives of a research project and the procedures of
30 investigation designed to reach those objectives.

31 (f) “Phase I drug” means a drug that is designated as a phase I
32 drug for testing purposes under the federal Food and Drug
33 Administration criteria in Part 312 of Subchapter D of Chapter I
34 of Title 21 of the Code of Federal Regulations.

35 SEC. 2. Section 3502 of the Penal Code is amended to read:

36 3502. (a) Biomedical research shall not be conducted on any
37 prisoner in this state.

38 (b) Notwithstanding subdivision (a), records-based biomedical
39 research using existing information, without prospective interaction
40 with human subjects, may be conducted consistent with this title.

1 *The use or disclosure of individually identifiable records pursuant*
2 *to this subdivision shall only occur after both of the following*
3 *requirements have been met:*

4 *(1) The research advisory committee established pursuant to*
5 *Section 3369.5 of Title 15 of the California Code of Regulations*
6 *approves of the use or disclosure.*

7 *(2) The prisoner provides written authorization for the use or*
8 *disclosure, or the use or disclosure is permitted by Section 164.512*
9 *of Title 45 of the Code of Federal Regulations.*

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