FRIENDS RESEARCH INSTITUTE, INC.
INSTITUTIONAL REVIEW BOARD (IRB)

State of California Requirements Pertaining to the Review of Human Subjects Research

A. Use of Prisoners as Research Subjects

Although the federal regulations state that biomedical research on prisoners is permitted, under California Penal Code, Section 3502, biomedical research on prisoners is prohibited in the State of California.

Behavioral research is 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. [California Penal Code Section 3505]

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. [California Penal Code Section 3508]

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. [California Penal Code Section 3504]

B. Age of Consent

The age of consent for participation in research is 18, the age at which Californians can contract and can consent to medical services. Parental permission must be sought for subjects under 18; exceptions to this must be granted by the IRB. [California Health and Safety Code Section 24173 (a)]

C. Reporting Suspected Abuse of Children, Elderly Individuals, and Others

Under California law, health professionals are required to report to appropriate authorities when there is good reason to believe that a child or an elderly or dependent adult has been neglected or abused. They are required to also report an injury that indicates possible abuse, or if they have personally treated a patient with injuries from an apparent assault [Child Abuse and Neglect Reporting Act, Cal. Penal Code, Section 11165 et seq.; Elder Abuse and Dependent Adult Civil Protection Act, Cal. Welfare. & Inst. Code, Section 15601 et seq.; Reports of Injuries, Cal. Penal Code, Section 11160 et seq.].

Failure of a health professional to file a required report is a misdemeanor, punishable by a fine of up to $1,000, or confinement in the county jail for up to six months, or both.

D. Protection of Human Subjects in Medical Experimentation Act of California

Since 1978, research in California has been governed by the Protection of Human Subjects in Medical Experimentation Act. The Act was amended in 2001 to clarify the hierarchy of those who can be a Legally Authorized Representative under the Common Rule. The Act provides for informed consent and for an Experimental Subjects Bill of Rights.

The Act provides an exemption for institutions holding an assurance with the Department of Health and Human Services. Because FRI has an assurance, it is allowed to follow the Common Rule elements of consent rather than California elements. However, FRI must still comply with the following sections:

(1) California Health and Safety Code Section 24172 [Experimental Subject's Bill of Rights]
(2) California Health and Safety Code Section 24176 [the penalties], and
(3) California Health and Safety Code Section 24178 [Addition for Legally Authorized Representative]

Under the Medical Experimentation Act, the term, *"Medical Experiment" means:*

(a) The severance or penetration or damaging of tissues of a human subject or the use of a drug or device, as defined in Section 109920 or 109952, electromagnetic radiation, heat or cold, or a biological substance or organism, in or upon a human subject in the practice or research of medicine in a manner not reasonably related to maintaining or improving the health of the subject or otherwise directly benefiting the subject.
(b) The investigational use of a drug or device.
(c) Withholding medical treatment from a human subject for any purpose other than maintenance or improvement of the health of the subject. [California Health and Safety Code Section 24174]

1. Subjects' Bill of Rights

Under federal regulations, all investigators are required to inform prospective subjects of their rights as research subjects. In addition, the State of California requires that all subjects enrolled in medical research receive a copy of the Research Subject's Bill of Rights. FRI Investigators conducting research in California are responsible for ensuring that subjects are provided with the FRI document "Rights of Human Subjects in Medical Experiments (see Appendix E in SOPs and Appendix A in Handbook)," in addition to the IRB approved informed consent form. The Rights of Subjects Form is to be signed and dated by the person signing the consent form. [California Health and Safety Code Section 24173 (a)]

2. Informed Consent

The following are additional required elements of the informed consent document for the State of California:

(1) If a placebo is to be administered or dispensed to a portion of the subjects involved in a medical experiment, all subjects of such experiment shall be informed of that fact; however, they need not be informed as to whether they will actually be administered or dispensed a placebo;
(2) An estimate of the expected recovery time of the subject after the experiment;
(3) The name, institutional affiliation, if any, and address of the person(s) actually performing and primarily responsible for the conduct of the experiment;
(4) The name of the sponsor/funding source, if any, or manufacturer if the experiment involves a drug or device, and the organization under whose aegis the experiment is being conducted; and
(5) The name, address, and phone number of an impartial third party, not associated with the experiment, to whom the subject may address complaints about the experiment.

3. Who Can Give Informed Consent

(1) The Subject or Legally Authorized Representative
(2) A conservator under the Probate code
(3) A designee under the Welfare and Institutions Code
(4) A gravely disabled person with no conservator can have a designee
(5) Someone else but only for
    1. Procedures intended to maintain or improve the subject's health, or
    2. Obtaining information about a pathological condition of the subject

4. Legally Authorized Representative

State and federal rules allow consent to be granted, under specific circumstances, by a legally authorized representative instead of the subject (e.g., parent for a minor). [California Statute on Consent of Minors]

5. Penalties

Any person who is primarily responsible for conduct of a medical experiment and who *negligently* allows such experiment to be conducted without a subject's informed consent, as provided above, shall be liable to such subject in an amount not to exceed one thousand dollars ($1,000), as determined by the court. The minimum amount of damages awarded shall be fifty dollars ($50).

Any person who is primarily responsible for the conduct of a medical experiment and who *willfully* fails to obtain the subject's informed consent, as provided above, shall be liable to such subject in an amount not to exceed five thousand dollars ($5,000) as determined by the court.

Any person who is primarily responsible for the conduct of a medical experiment and who *willfully* fails to obtain the subject's informed consent, as provided above, *and thereby exposes a subject to a known substantial risk of serious injury*, either bodily harm or psychological harm, shall be guilty of a misdemeanor punishable by imprisonment in the county jail for a period not to exceed one year or a fine of ten thousand dollars ($10,000), or both.

E. Research Advisory Panel of California

California requires proposed research projects involving certain opioid, stimulant, and hallucinogenic drugs classified as Schedule I and Schedule II controlled substances to be pre-reviewed and authorized by the Research Advisory Panel of California (RAP of C) in the Attorney General's Office.

Researchers must submit applications to the panel for research projects involving:
(1) Any Schedule I controlled substance;
(2) Human research using any Schedule I or Schedule II controlled substance; or
(3) Research for the treatment of drug abuse using any drug, scheduled or not.

Similar to the IRB, the RAP of C primarily seeks to ensure the safety and protection of participating human research subjects and adequate security of the controlled substances used in the study. The panel members evaluate the scientific validity of each proposed project, and may reject proposals where the research is poorly conceived, would produce conclusions of little scientific value, or would not justify the exposure of California subjects to the risk of the research.

FRI investigators conducting research subject to review by the RAP of C must provide the IRB with proof of the RAP of C approval, before final IRB approval is granted.

For more information about the RAP of C, please visit http://caag.state.ca.us/research, or contact:

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