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– Notices –

California Experimental Subject's Bill of Rights for California Research Sites

California law[1] requires each subject or his/her representative to read, sign, and date the California Experimental Subject's Bill of Rights before consenting to take part in research. You may use the document included with your approval documents.

Required Font Size for HIPAA Authorization for California Research Sites

California law[2] require HIPAA authorization language to be presented in 14-point font. To help your site maintain compliance with California State regulations, Aspire IRB has updated the font size of the HIPAA language in your consent form to 14 point.

California Research Advisory Panel Pre-Review Requirements

California law[3] requires proposed research projects using Schedule I and Schedule II controlled substances as main study drugs to be pre-reviewed and authorized by the Research Advisory Panel of California in the Attorney General's Office

[1] California Health and Safety Code §§ 11213, 11480, and 11481
[2] California Health and Safety Code § 24173
[3] California Civil Code § 56.11

CALIFORNIA EXPERIMENTAL SUBJECT'S BILL OF RIGHTS

Any person who is requested to consent to participate as a subject in a research study involving a medical experiment, or who is requested to consent on behalf of another has the right to:

(a) Be informed of the nature and purpose of the experiment.

(b) Be given an explanation of the procedures to be followed in the medical experiment and any drug or device to be used.

(c) Be given a description of any attendant discomforts and risks reasonably to be expected from the experiment, if applicable.

(d) Be given an explanation of any benefits to the subject reasonably to be expected from the experiment if applicable.

(e) Be given a disclosure of any appropriate alternative procedures, drugs, or devices that might be advantageous to the subject, and their relative risks and benefits.

(f) Be informed of the avenues of medical treatment, if any, available to the subject after the experiment or if complications should arise.

(g) Be given an opportunity to ask any questions concerning the experiment or other procedures involved.

(h) Be instructed that consent to participate in the medical experiment may be withdrawn at any time, and the subject may discontinue in the medical experiment without prejudice.

(i) Be given a copy of a signed and dated written informed consent form when one is required.

(j) Be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion or undue influence on the subject's decision.

Signature of adult subject capable of consent, child subject's parent, individual authorized to consent to the child subject's general medical care, or adult subject's legally authorized representative	Date