



**OFFICE OF RESEARCH AND DEVELOPMENT
VETERANS HEALTH ADMINISTRATION**

**ORD Frequently Asked Question (FAQ) on Required Signatures and Dates for Subjects or
Subjects' Legally Authorized Representatives (LARs) on the California's Experimental
Subject's Bill of Rights**

Date: October 17, 2024

This is a new FAQ.

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The Office of General Counsel, Specialty Team Advising Research (OGC STAR) and the VHA Office of Research and Development (ORD), are providing guidance on the following query:

Question: Are VA subjects or the subjects' legally authorized representatives (LARs) required to sign and date California's Experimental Subject's Bill of Rights when the VA human subjects study requires following California state laws for informed consent?

Response: No. VA subjects or their legally authorized representatives (LARs), if the IRB approves surrogate consent by LARs, are not required to sign and date California's Experimental Subject's Bill of Rights for a VA human subjects study following California state laws for informed consent. However, a copy of California's Experimental Subject's Bill of Rights must be provided to subjects or their LARs for these VA studies if the VA study meets the definition of a "medical experiment".

Rationale: As background to the above response, Federal laws apply at VA facilities. Consequently, VA looks to federal law to determine whether there is a basis to apply state law. VA, as a federal department, adopted the Federal Policy for the Protection of Human Subjects, also referred to as the "Common Rule", in 38 C.F.R. Part 16. Within the Common Rule, 38 C.F.R. § 16.101(f) reads:

This policy does not affect any state or local laws or regulations (including tribal law passed by the official governing body of an American Indian or Alaska Native tribe) that may otherwise be applicable and that provide additional protections for human subjects.

This citation within the Common Rule provides a basis for VA to follow state laws that are otherwise applicable and provide additional protections for human subjects.

The California Health and Safety Code's requirement in section [24173\(a\)](#) to obtain a signed and dated Experimental Subject's Bill of Rights is not applicable to VA because there are no additional protections for human subjects by requiring a dated signature to that document.

The California Health and Safety Code section [24178](#) exempts from the signature and date requirement investigators conducting medical experiments¹ at institutions that hold a Federalwide Assurance (FWA) where consent is obtained in accordance with the Common Rule. All research involving human subjects approved by the Department of Veterans Affairs requiring IRB review can only be conducted at VA facilities with an approved Federalwide Assurance. Therefore, any VA human subjects study meeting the definition of a Medical Experiment under the California Health and Safety Code will be conducted under an FWA and in accordance with federal regulations governing informed consent.

Notwithstanding, per California Health and Safety Code section [24172](#), VA is required to meet California state law requirements for providing a copy of the California's Experimental Subject's Bill of Rights to the subject, if the VA research study constitutes a Medical Experiment under the meaning of the California Health and Safety Code.

Implication: VA human subjects studies required to adhere to California state laws for informed consent must provide a copy of California's Experimental Subject's Bill of Rights to the VA subject (or VA subject's LAR if surrogate consent is approved). However, the Experimental Subject's Bill of Rights is not required to be signed and dated by any individual.

"Medical Experiment" means:

- (a) The severance or penetration or damaging of tissues of a human subject or the use of a drug or device [...], 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 [under the Food, Drug, and Cosmetic Act and otherwise in accordance with the California Health & Safety Code].
- (c) Withholding medical treatment from a human subject for any purpose other than maintenance or improvement of the health of the subject.

California Health & Safety Code section [24174](#) (hereinafter "Medical Experiment").