

—Notice —

Experimental Subject's Bill of Rights for California Research Sites

In order to help your site maintain compliance with California State regulations, WIRB has included the California Experimental Subject's Bill of Rights in your consent form(s). The applicable regulation reads as follows:

- (a) The subject or subject's conservator or guardian, or other representative, as specified in Section 24175, is provided with a copy of the experimental subject's bill of rights, prior to consenting to participate in any medical experiment, containing all the information required by Section 24172, and the copy is signed and dated by the subject or the subject's conservator or guardian, or other representative, as specified in Section 24175.
West's Ann.Cal.Health & Safety Code § 24173

It is WIRB's procedure to include the Experimental Subject's Bill of Rights as the last page of the consent form(s) to aid in keeping the two documents together during filing into your site's regulatory binder. However, the subject must read and sign the Bill of Rights prior to consenting to participate in the research study.

Required Font Size for HIPAA Authorization for California Research Sites

California state regulations require HIPAA authorization language to be presented in 14 point font. To help your site maintain compliance with California State regulations, WIRB has updated the font size of the HIPAA language in your consent form to 14 point. The applicable regulation reads as follows:

An authorization for the release of medical information by a provider of health care, health care service plan, pharmaceutical company, or contractor shall be valid if it:

- (a) Is handwritten by the person who signs it or is in a typeface no smaller than 14-point type.

West's Ann.Cal.Civ.Code § 56.11

If you have questions, please contact WIRB client services at 1-800-562-4789.