



MEMO

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CONFIDENTIAL

Date: 30 January 2009

To: California Investigators for Whom CGIRB Serves as the IRB of Record

From: Tabitha K. Westbrook, CQA, RQAP-GCP, Manager, Quality Assurance & Regulatory Compliance

Re: California Experimental Subject's Bill of Rights

In an effort to provide the most meaningful consent documents to subjects, CGIRB has made the decision to no longer include the California Experimental Subject's Bill of Rights in its template subject information and consent form (SICF). Instead, CGIRB believes that it is in the best interest of the subjects to have the investigators obtain the required documentation directly from the information published by the State of California. This will help assure that subjects are routinely consented in accordance with the applicable California state law.

California's "Protection of Human Subjects in Medical Experimentation Act," California Health and Safety Code, Section 24170 (a) requires that the Experimental Subject's Bill of Rights be given to subjects prior to consenting [ie, presentation and signing of the study information and consent form (SICF)] to be in a clinical research study. Guidance posted on the web site for The Office of the Attorney General (<http://ag.ca.gov/research/consent.php>) also states that a copy of the California Experimental Subject's Bill of Rights be included in the consent form. CGIRB does not provide the California Experimental Subject's Bill of Rights as part of the SICF template and expects that investigators provide the copy of the document as part of the SICF during the consent process [such copy is signed and dated by the subject or the subject's conservator or guardian, or other representative, as specified in Section 24175]. Links to both the above-listed web site and the California Experimental Subjects Bill of Rights are posted on CGIRB's web site (www.cgirb.com), under Investigators/Regulatory Guidance for your convenience.

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