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CONFIDENTIAL

Date: 24 Feb 2011
To: California Investigators for Whom CGIRB Serves as the IRB of Record
From: Tita Simmons, 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 24173 \(a\)](#) requires that the Experimental Subject's Bill of Rights be given to subjects prior to consenting [i.e. presentation and signing of the study SICF] to be in a clinical research study. [California Informed Consent Guidelines](#) posted on the website for the State of California Department of Justice, Office of Attorney General 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]. Links to [California Informed Consent Guidelines](#), the [California Experimental Subject's Bill of Rights](#) and California's Health and Safety Code, Section [24172](#) and [24173](#) are embedded within this document and posted on CGIRB's website (www.cgirb.com), under Regulatory Guidance for your convenience.