UNIVERSITY OF CALIFORNIA, SAN DIEGO
HUMAN RESEARCH PROTECTIONS PROGRAM

Frequently Asked Questions— FDA Final Rule: ClinicalTrials.gov Consent Wording

Q. What is this "Final Rule" all about?

A. The FDA has amended the informed consent regulations, 21 CFR 50.25, to include a "new" section. This section, 21 CFR 50.25***(c)***, states, "When seeking informed consent for applicable clinical trials … a statement shall be provided to each clinical trial subject in informed consent documents and processes. This will notify that clinical trial subject that clinical trial information has been or will be submitted for inclusion in the clinical trial registry databank…." The FDA also notes that the amendment "is designed to promote transparency of clinical research to participant and patients."

Q. What is the specific statement that is required?

A. "A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time."

Q. Can this wording be changed?

A. No. The FDA has indicated that it is essential "that one common message appear consistently in all informed consent documents and processes."

Q. When must this wording be included in the consent?

A. March 7, 2012. HOWEVER—it is only mandatory for trials initiated after March 7, 2012. For the purposes of this rule, a trial is "initiated" if the sponsor/investigator has had any informed consent documents cleared or approved by an IRB. The requirement is to be applied prospectively. The date of the "cleared" consent is the approval release date found on the initial approval letter from the IRB.

Q. Will re-consenting of subjects be required?

A. Re-consenting of subjects of trials initiated before the compliance date solely for the new requirement will not be required. The additional wording can be included where a revision to the consent and re-consenting is being done for other reasons but is not required.

Q. What if the use of a short form is approved or a waiver of documentation of informed consent under 21 CFR 56.109 has been granted by the IRB?

A. The FDA notes, "When a short form written consent document is chosen (Sec. 50.27(b)(2)), a short form and written summary must be provided to the clinical trial participant. All of these are considered 'informed consent documents' and must contain the new statement…. For example, if an IRB waives the requirement for a signed written consent form under Sec. 56.109(c)(1), and requires 'the investigator to provide subjects with a written statement regarding the research,' this written statement is considered a part of the documentation of ensuring the informed consent of the participant and thus, it must include the new statement (Sec. 56.109(d))."

Q. What is the "registry databank"?

A. Since 2007, registration of applicable clinical trials has been required per the FDA Amendments Act FDAAA, 42 U.S.C. 282(j)(1)(A), section 402(j)(1)(A) of the PHS Act. The FDA notes, the databank "is

the clinical trial registry databank maintained by the National Institutes of Health/National Library of Medicine (NIH/NLM), which was created by statute. The submission of clinical trial information to this databank also is required by statute."

Q. What is an "applicable" clinical trial?

A. An applicable drug clinical trial means a controlled clinical investigation, other than a phase 1 clinical investigation, of a drug subject to section 505 of the Federal Food, Drug, and Cosmetic Act or to section 351 of the Public Health Service Act. an applicable device clinical trial means a prospective clinical study of health outcomes comparing an intervention with a device subject to section 510(K), 515, 520(m) of the Federal Food, Drug, and Cosmetic Act again as a control in human subjects (other than a small clinical trial to determine the feasibility of a device, or a clinical trial to test prototype devices where the primary outcome measure relates to feasibility and not to health outcomes); and a pediatric postmarket surveillance as required under section 522 of the Federal Food, Drug, and Cosmetic Act.

Q. Has the UCSD consent template be updated to include this wording?

A. Yes. The updated UCSD consent document can be found on the Forms page. You are also reminded that 21 CFR 50.25(a)(5) includes that the consent must include a statement "describing the extent, if any, to which confidentiality of records identifying the subject will be maintained and that notes the possibility that the Food and Drug Administration may inspect the records."

Q. Where can you find more information?

A. The Final Rule can be accessed at http://edocket.access.gpo.gov/2011/2010-33193.htm. More information about clinical trial registration and "applicable clinical trials" can be found at http://prsinfo.clinicaltrials.gov/fdaaa.html and http://prsinfo.clinicaltrials.gov/ElaborationsOnDefinitions.pdf.