FDA Issues Guidance on New Informed Consent Rule

In 2007, the Food and Drug Administration (FDA) issued regulations under the Food and Drug Administration Amendments Act of 2007 requiring that all “applicable clinical device trials” and “applicable clinical drug trials” (both defined below) initiated after September 27, 2007, must be registered on [http://www.ClinicalTrials.gov](http://www.ClinicalTrials.gov) not later than 21 days after the first patient is enrolled. On January 4, 2011, FDA issued a final rule modifying the informed consent requirements (76 Fed. Reg. 256 (Jan. 4, 2011)). On February 9, 2012, FDA issued the Guidance, “Questions and Answers on Informed Consent Elements, 21 CFR § 50.25(c).” This Guidance is intended to help sponsors, investigators and Institutional Review Boards (IRBs) better understand the new informed consent requirement set forth in 21 CFR 50.25(c).

The January 2011 Final Rule amended FDA’s informed consent regulations to require that informed consent documents and processes for applicable drug (including biological products) and device clinical trials include a specific statement (below) that clinical trial information will be entered into the clinical trial registry databank maintained by the National Institutes of Health/National Library of Medicine (NIH/NLM). It is applicable to all clinical trials initiated on or after [March 7, 2012](#).

The Guidance explains that the following statement must be reproduced word-for-word in informed consent documents for applicable clinical trials:

“A description of this clinical trial will be available on [http://www.ClinicalTrials.gov](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.”

This statement does not have to be located in any particular section of the consent form. It may be translated if potential participants are non-English speaking.

If an IRB has already approved any informed consent documents for the applicable clinical trial prior to March 7, 2012, then the trial will be considered “initiated” before the compliance date, and the new statement will not be required. Even if documentation of informed consent is waived under the applicable regulations (e.g., the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside the research context), to the extent the IRB requires the investigator to provide subjects with a written statement
regarding the research, the written statement is considered a part of the documentation of ensuring the informed consent of the participant and, thus, must include the new statement. Similarly, if an IRB requires the investigator to provide subjects with an oral presentation of the research, the statement should be made to subjects.

The trial is an “applicable clinical device trial” if (i) the trial prospectively compares a device-based intervention subject to FDA regulation against a control in human subjects; or (ii) the trial is a pediatric post-market surveillance trial. The trial is an “applicable clinical drug trial” if the trial is a controlled clinical investigation, other than a Phase I clinical investigation, of a drug subject to FDA regulation. For the purposes of this definition, a “clinical investigation” is “any experiment in which a drug is administered or dispensed to, or used involving, one or more human subjects.”

Currently excluded from the definition of “applicable clinical device trials” are:

(1) small feasibility trials and larger clinical trials of prototype devices with a primary measure of feasibility rather than health outcomes; and

(2) a device trial in which the trial includes only de-identified human specimens and does not include “human subjects.”

Currently excluded from the definition of “applicable clinical drug trials” are:

(1) Phase 1 clinical investigations; and

(2) uncontrolled clinical investigations of drugs or devices.

If you would like to receive future Health Care Advisories electronically, please forward your contact information including e-mail address to healthcare.advisory@alston.com. Be sure to put “subscribe” in the subject line.

For further information, please do not hesitate to contact any of the following:

**Atlanta Office**

Donna P. Bergeson  
404.881.7278  
donna.bergeson@alston.com

Angela T. Burnette  
404.881.7665  
angie.burnette@alston.com

Dawnmarie R. Matlock  
404.881.4253  
dawnmarie.matlock@alston.com

Kim McWhorter  
404.881.4254  
kim.mcwhorter@alston.com

D’Andrea J. Morning  
404.881.7538  
dandrea.morning@alston.com

Robert D. Stone  
404.881.7270  
robert.stone@alston.com

Michelle A. Williams  
404.881.7594  
michelle.williams@alston.com

Esther Yu  
404.881.4240  
esther.yu@alston.com

**Washington Office**

Cathy L. Burgess  
202.239.3648  
cathy.burgess@alston.com

Brendan Carroll  
202.239.3216  
brendan.carroll@alston.com

Marc J. Scheineson  
202.239.3465  
marc.scheineson@alston.com

Donald E. Segal  
202.239.3449  
donald.segal@alston.com

Julie K. Tibbets  
202.239.3444  
 julie.tibbets@alston.com