Clinical Trial
Informed Consent Element
Effective March 07, 2012

Final Rule Issued by FDA
The Food and Drug Administration (FDA) issued a final rule on January 04, 2011 that amends 21 CFR § 50.25 and the requirements for informed consent documentation and process in FDA-regulated clinical trials of drugs, biological products, and medical devices

The final rule responds to section 801 of the FDA Amendments Act of 2007 (FDAAA) which requires registration and results posting in the federal data bank, ClinicalTrials.gov, for "applicable clinical trials" of FDA-regulated drugs and medical devices.

The compliance date for this rule is March 07, 2012 for clinical trials that are initiated on or after the compliance date. Modification of consent processes and "re-consent" will not be required for "applicable clinical trials" initiated prior to March 12, 2012.

Statement for Informed Consent
The final rule requires the following statement (cannot be altered) to be included in the informed consent documents and process of "applicable clinical trials" for both drugs (including biological products) and medical devices:

"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."

For assistance in determining whether your study is an "applicable clinical trial" please see the "What is an Applicable Clinical Trial?" checklist found on the BMH IRB webpage.

BRONSON