Summary

Registration of Studies in ClinicalTrials.gov

For details and guidance, please see associated RAC website and/or contact 294-5189.

FDAMA requires registration of any study as of 02/29/2000 involving one or more of the following:

- Drugs and biologics to treat serious or life-threatening diseases and conditions where the likelihood of death is high unless the course of the disease is interrupted
- Group C cancer drug (as defined by the National Cancer Institute)

FDAAA requires registration of any study ongoing or initiated after 9/27/2007 involving drugs, biologics and devices in one or more of the following categories:

- Phase II, III and IV clinical trials
- Controlled trials with health outcomes
- Pediatric post-market surveillance studies
- Studies conducted under an IND/IDE

Warning: Penalties for failure to register a FDAAA study will include a $10,000 warning letter to become compliant in 30 days. If not compliant in 30 days, a $10,000 a day fine will be assessed until the study is posted on ClinicalTrials.gov registry. If the study is funded by the NIH, the NIH can request the return of NIH funds for the entire project, part of the project, or any funded projects.

CMS requires, effective January 1, 2014, that the 8-Digit Clinical Trial Number (NCT) from the ClinicalTrials.gov registry be included on claims for items and services provided in clinical trials that are qualified for coverage in the Medicare NCD Manual. This includes claims with the following codes:

- Condition code 30;
- ICD-9 code of V70.7/ICD-10 code Z00.6 (in either the primary or secondary positions) and
- Modifier Q0 and/or Q1, as appropriate (outpatient claims only).

Thus, any study must be registered that requires billing out for services provided to beneficiaries during their participation in a clinical trial, a clinical study, or a registry. Any bills not containing an 8-digit clinical trial number will be returned as unprocessable to the provider for inclusion of the trial number.

NIH encourages (but does not require) registration of all NIH-supported clinical trials, regardless of whether or not they are subject to FDAAA. Note: UF also encourages registration of human subject research projects that involve a medical intervention for a health outcome.
ICMJE
The ICMJE requires, and recommends that all medical journal editors require, registration of clinical trials in a public trials registry at or before the time of first patient enrollment as a condition of consideration for publication. Editors requesting inclusion of their journal on the ICMJE website list of publications that follow ICMJE guidance should recognize that the listing implies enforcement by the journal of ICMJE’s trial registration policy.

The ICMJE defines a clinical trial as any research project that prospectively assigns people or a group of people to an intervention, with or without concurrent comparison or control groups, to study the cause-and-effect relationship between a health-related intervention and a health outcome. Health-related interventions are those used to modify a biomedical or health-related outcome; examples include drugs, surgical procedures, devices, behavioral treatments, educational programs, dietary interventions, quality improvement interventions, and process-of-care changes. Health outcomes are any biomedical or health-related measures obtained in patients or participants, including pharmacokinetic measures and adverse events. The ICMJE does not define the timing of first patient enrollment, but best practice dictates registration by the time of first patient consent.

Acronyms
CMS – Centers for Medicare & Medicaid Services
FDAAA – Food and Drug Administration Amendments Act of 2007
FDAMA – Food and Drug Administration Modernization Act of 1997
ICMJE – International Committee of Medical Journal Editors
IDE – Investigational Device Exemption
IND – Investigational New Drug
NCD – Medicare National Coverage Determination (NCD) Manual
NIH – National Institutes of Health