Purpose
Washington University (WU) is committed to the public dissemination of the results of research conducted by its faculty. This guideline describes WU efforts to support the requirement to register clinical trials in accordance with public law and sponsor requirements. The Food and Drug Administration Amendments Act (FDAAA) of 2007 (US Public Law 110-85) requires the registration of clinical trials using ClinicalTrials.gov. The NIH also requires that all clinical trials receiving full or partial funding must be registered. In addition, many scientific journals also require the registration of clinical trials as a requirement for publication.

Position Statement
Washington University faculty and staff who execute clinical trials subject to the FDA policy, the NIH policy, or the ICMJE policy should register (or insure the registration of) all trials as required.

Requirements
Clinical Trials must be registered if any of the following 3 conditions are present:

1. The FDAAA of 2007 requires the registration of the following types of studies:
   
   - Controlled, clinical investigations of drugs and biologics subject to FDA regulation, other than Phase I trials; and
   - Controlled trials with health outcomes of devices subject to FDA regulation, other than small feasibility studies, but including pediatric postmarket surveillance of devices ordered under section 522 of the Federal Food, Drug and Cosmetic Act.

   In addition, the FDAAA requires posting of clinical trial results within 12 months of closing the trial.

2. The NIH requires that all clinical trials receiving full or partial funding be registered. A statement to that effect (including the National Clinical Trial number assigned by ClinicalTrials.gov) must be in the Human Subject Portion of the renewal or competing continuation applications. New applications must indicate that any proposed clinical trial will be registered.

3. The policy of the International Council of Medical Journal Editors (ICMJE) requires the registration of all “clinically directive” trials—trials that test a clinical hypothesis about health outcomes. These include any trials that assign human subjects to intervention and comparison groups to study cause-and-effect relationships between interventions and health outcomes. Participating journals may refuse publications if the trials are not registered.

Procedures
The Center for Applied Research Sciences provides information and assistance to investigators who are registering their clinical trials. WU registration procedures and data requirements are posted at http://research.wustl.edu/PoliciesGuidelines/Pages/WUSTLPoliciesGuidelines.aspx. Frequently asked questions and key information are posted as well as flow charts to help determine which trials should be registered and who is the responsible party for registration.

Oversight/Sanctions
The primary responsibility for registration of clinical trials and the posting of results resides with the Principal Investigator. Registration of applicable trials by WU investigators will be confirmed during any quality assurance activity.

Penalties for responsible parties who fail to register applicable clinical trials are significant and may include civil monetary penalties and, for federally-funded trials, the withholding or the recovery of grant funds.