The JHSPH requires that all clinical trials shall be registered at http://www.clinicaltrials.gov. The definition of a clinical trial for purposes of this policy is, “Any research study that prospectively assigns human participants or groups of humans to one or more health related interventions to evaluate the effects on health outcomes.” Health outcomes include any biomedical or health-related measures, including pharmacokinetic measures and adverse events. This policy incorporates requirements imposed by the September, 2007 FDA Amendments Act, which affected new and ongoing trials as of January 25, 2008. This policy additionally incorporates the International Committee of Medical Journal Editors (ICMJE) policy applying to all trials, including preliminary and Phase 1 studies, beginning enrollment on or after July 1, 2008.

The JHSPH PI should consult with commercial sponsors to assure that posting of a trial is in accord with terms of the study contract.

Clinical trial registration information will be requested with the initial IRB application. If the trial has not been registered at that time, the PI must confirm trial registration at the time a continuing review application is submitted. The JHSPH IRB may approve a continuing review application for a study that has not been registered, but IRB staff will notify the Institutional Official (IO). The IO will contact the PI to indicate that new enrollment may not proceed until the trial has been registered, or that the IO accepts the delay in registration due to extenuating circumstances.