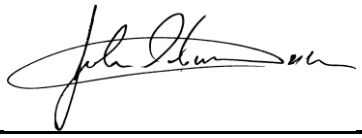
KESSLER FOUNDATION

Policies and Procedures Manual
IRB

SUBJECT: Registering Clinical Trials at <ClinicalTrials.gov>	**POLICY # 5036**
APPROVED: **Richard J. Greene, M.D., Ph.D.** **IRB Chair**  **John DeLuca, Ph.D.** **Senior Vice President for Research** 	**EFFECTIVE DATE:** **March 29, 2006** **REVISED DATE:** **April 10, 2014**

PURPOSE

The registration of clinical trials in a free, publicly accessible forum can provide patients, physicians, researchers and funding agencies with information on what trials are currently being carried out. Through a trial registry patients (and their physicians) can learn of trials for which they may be eligible. And trial registration can avoid duplication of research efforts and can help counteract the bias that occurs when studies with negative results go unpublished.

The NIH has developed a web-based trial registry <ClinicalTrials.gov>. Starting in 2007, the FDA required all pre-marketing Phase 2 and 3 trials of drugs and devices to be registered on this site. Moreover, many scientific journals will not publish the results of clinical trials that have not been registered on a publicly accessible trial registry before the firs subject is enrolled. This is the formal policy of the International Committee of Medical Journal Editors (ICMJE) (1) and has been adopted by many U.S. and international journals in the biomedical and behavioral sciences.

The purposes of this Kessler Foundation IRB policy is to comply with the FDA and the ICMJE policies by requiring all applicable clinical trials be registered on <ClinicalTrials.gov>.

POLICY

The Kessler Foundation's IRB requires that all research studies that meet the ICMJE definition of a clinical trial be registered on <ClinicalTrials.gov> before the first subject is enrolled. For this purpose we have adopted the ICMJE definition of a clinical trial: "Any research project that prospectively assigns human subjects to intervention and comparison groups to study the cause-and-effect relationship between a medical intervention and a health outcome. By medical intervention we mean

any intervention used to modify a health outcome. This definition includes drugs, surgical procedures, devices, behavioral treatments, process of care changes, and the like. …The trial must have at least one prospectively assigned concurrent control or comparison group." (1)