Investigator Single Site Compliance with ClinicalTrials.gov (CTG) Consent and Website Posting Requirements: The First Two Years
Debra G. Tice, MS; Tinatin Kiguradze; Michael Kelley, BS, CIP; Eileen Yates, MS, CIP; Heather Gipson, JD, MA; Jeff Lunt; Barb Ferry; Monalee Shah; Sigmund Weitzman; Steven Belknap; Dennis West, PhD, CIP
Northwestern University

Submission Type: Scientific
Topic Area: Regulations and Guidance
Poster Number: 94

Problem Statement: IRBs have been mandated to review consent forms containing: "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 the Web site at any time." The newly mandated consent language, and subsequent compliance of posting of the trial by the principal investigator (PI) to CTG, poses a new burden to the IRB.

Description of Research: We assessed compliance for the two year period beginning with March 7, 2012, by identifying from 1,681 biomedical projects, a total of 92 projects that were declared by PI to be: 1) a clinical trial; 2) single site; 3) requires written consent; and 4) indicated by PI that it will be posted on CTG. Trials reported to IRB as never initiated were excluded. Of over 4,500 total projects (both biomedical and social/behavioral science projects), 1,681 were IRB-approved biomedical projects during this two year period, and 92 met study criteria. We found that 77 of 92 (84%) trials contained the mandated consent language relevant to CTG. Of these, only 50 of the 77 trials were among those posted on CTG. Moreover, of the 92 (58%) trials meeting criteria for evaluation in this study, only 53 (58%) were posted on CTG website. In conclusion, this work indicates that PIs are mostly compliant during this early implementation period for required consent language consistent with federal regulations. However, discrepant numbers for those PIs presumed to be the designated Responsible Party for CTG, as well as the posting of the trial to CTG, may very well be related to multi-factorial delays in contractual agreements, delays in initiation of the trial, and a whole host of confounding factors that may explain the absence of a posting that reconciles with the IRB-approved trial, despite the PI declaring in the IRB submission that the trial will be posted on CTG. Limitations include: no assessment for the required posting of results, as it is too early in the implementation of these regulations to obtain a sizeable sample. Further, trials that were never initiated due to numerous confounding factors such as no execution of agreement or staff turnover were excluded if reported to IRB, but, if this was not reported to IRB, then such a trial would not have been detected for exclusion.