INVESTIGATOR SINGLE SITE COMPLIANCE WITH CLINICALTRIALS.GOV REQUIREMENTS: THE FIRST TWO YEARS
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INTRODUCTION
As of January 4, 2011 (76 FR 256), FDA published a final regulation (21 CFR § 50.25(c)) requiring that informed consent documents and processes for applicable drug, biologics and device clinical trials include a specific statement that clinical trial information will be entered into a database. The submission of clinical trial information to this data bank also is required by statute. The new regulation is designed to promote transparency of clinical research to participants and the public at large.

Subsequent to this regulation, as of March 7, 2012 consent forms for applicable clinical trials must contain the following language:

“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 this Web site at any time.”

Although administered by FDA, clinical trial registration has also been invoked by The International Committee of Medical Journal Editors (ICMJE) as a condition for publication of research results.

As of November 19, 2014, further steps were taken to enhance transparency of clinical trials¹ as this proposed rulemaking further expands reporting requirements². Consequently, our aim was to assess compliance with this new consent language requirement and to determine whether or not the specified clinical trials were consistent with registration on the ClinicalTrials.gov website as indicated in the regulation, since implementation of this new regulations is now at the two year mark.

RESEARCH QUESTION
This retrospective analysis is designed to determine:

✓ Whether the informed consent (ICF) did or did not contain the FDA-required language about ClinicalTrials.gov
✓ Whether or not the specified clinical trial was registered on the ClinicalTrials.gov web site as required.

METHODS
All IRB-approved biomedical research studies over the two year period (03-07-2012 to 03-06-2014) (n=4650) since implementation of the consent language requirement, contained in an electronic database at a single large urban institution were surveyed to identify all single center clinical trials that were declared by the PI as a project to be registered on the ClinicalTrials.gov website. The ClinicalTrials.gov website was then surveyed to ascertain that the project was or was not registered on ClinicalTrials.gov as indicated by the PI in the IRB application.

RESULTS
✓ Of 4650 biomedical research studies, 92 met criteria for evaluation.
✓ 77 of 92 (84%) projects indicated by the PI to be registered on ClinicalTrials.gov did contain the mandated consent form language regarding ClinicalTrials.gov in the IRB-approved consent form (See Figure 1). Only 53 (58%) of the 92 projects were registered on ClinicalTrials.gov during the time frame utilized for this study.
✓ Of note, there were three projects of the 92 trials (3%) that did not contain the FDA required consent language about ClinicalTrials.gov in the IRB-approved ICF even though these three projects were registered on ClinicalTrials.gov.

CONCLUSIONS
Mandated consent form language and mandated registration on ClinicalTrials.gov website, now at the two year mark since implementation, show a high rate of compliance for consent disclosure to subjects. However, there was a lower rate of consistency with the web site registration requirement, apparently related to multiple influencing delaying factors.

REFERENCES