Registering with Clinical trials.gov

Onn 9t/s Act of

2007. Under the Final Rule:

- Results information is required for ALL applicable dinical trials that are required to register, not
 just those for which the drug, biological, or device products studied are approved. The standard
 deadline for results information submission is no longer than one year after the primary
 completion date.
- 3. Corrections to submitted information will be required within 15 days (for registration information) and 25 days (for results information). Responsible parties will be required to correct or address within 15 days (for registration information) and 25 days (for results information) any errors, deficiencies and /or inconsistencies that are identified during the quality control review process.

The new NIH policy is similar to the Final Rule, except that NIH now requires that all NIH-funded dinical trials register and submit results. Thus, the NIH policy now covers more types of trials, including phase 1 studies, small feasibility studies, and trials that do not involve any FDA-regulated product, such as trials involving only behavioral interventions.

The Final Rule and the new NIH policy is effective 1/18/2017.

Studies that must be registered and submit results by law are call

The Final Rule and FDAAA have the same definition of Applicable Clinical Trial. These trials generally include:

Interventional Trials of Drugs and Biologics
Interventional Trials of Devices, other than device feasibility studies
Pediatric Post-Market Surveillance Studies

Who is Responsible for Registration and Up-Dating Clinical Trials on ClinicalTrials.gov

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- 1. A person who initiates a clinical investigation, but who does not actually conduct the investigation, i.e., the test article is administered or dispensed to or used involving, a subject under the immediate direction of another individual. A person other than an individual (e.g., corporation or agency) that uses one or more of its own employees to conduct a clinical investigation it has initiated is considered to be a sponsor, and the employees are considered to be investigators.
- A sponsor-investigator is an individual who both initiates and actually conducts, alone or with others, a dinical investigation, i.e., under whose immediate direction the test article is administered or dispensed to, or used involving, a subject. The term does not include any person other than an individual, e.g., corporation or agency.

eing conducted

under an investigational new drug application (IND) or investigational device exemption (IDE), then the IND/IDE holder is considered to be the person or entity who initiated the trial and, therefore, is the sponsor (regardless of how the tri

The record will then be sent to the TTUHSC ClinicalTrials.gov administrator for review, approval, and release of the record to the ClinicalTrial.gov quality review team.

The PRS Administrator

ClinicalTrials.gov for review). It is important to note that this is a two-step process. Both the PRS Administrator at TTUHSC and the reviewers at ClinicalTrials.gov will often request changes to the record. The record will not be released until all the changes have been completed. It is important to allow enough time for both the PRS Administrator and ClinicalTrials.gov to review.

Records are made available to the public through the ClinicalTrials.gov website within 2 to 5 days of release, following a review by ClinicalTrials.gov.

Results Submission Requirements

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the purposes of the final collection of data for the primary outcome. This occurs whether the clinical trial was concluded according to the pre-specified protocol or was terminated. Principal Investigators must complete the required fields with meaningful entries and are encouraged to complete all optional data elements where appropriate to their study. The PRS Administrator will set up a meeting with ClinicalTrial.gov analysts to assist the Principal Investigator if additional information is needed to submit results.

Registration and Publication in Medical Journals

Medical journals following the International Committee of Medical Journal Editors (ICMJE) guidelines require registration as a condition of publication. Please note that the ICMJE guidelines require registration of trials of all intervention types, including trials that do not involve any FDA-regulated product, such as trials involving only behavioral interventions. Additionally, phase 1 drug studies and device feasibility studies must be registered per the ICMJE guidelines.

Noncompliance