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

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

A breach of this policy by an investigator or research personnel providing study information to ClinicalTrials.gov may includeid 6i10(no)4(t)-9(5(i-8m)-21(i)e0nd)4(t)o:0)]TJET EMC P <MCID 15>BDC BT1 0 0 1 249.28 25 Tm[( )]TJ