**GUIDANCE 6**

**CLINICAL TRIALS.GOV REGISTRATION GUIDANCE**

1. All clinical trials must be registered with Rowan University Clinical Trials and Research Office Administration.
2. **Public Law 110-85:** [**https://www.congress.gov/110/plaws/publ85/PLAW-110publ85.pdf**](https://www.congress.gov/110/plaws/publ85/PLAW-110publ85.pdf)**.**
3. The FDA Amendments Act of 2007 requires all clinical trials be registered in a public database. The Act of 2007 contains trial registration requirements at ClinicalTrials.gov. Consequences of not registering can include monetary and civil penalties. Additionally, many journals require that the trials have been registered before papers will be considered for publication. RowanSOM requires investigators to register all Investigator-initiated and National Institute of Health (NIH) trials into the University’s profile at www.clinicaltrials.gov. Industry sponsored studies are registered by the Sponsor**.**
4. **The following links provide details about clinical trials.gov**
5. The law: The recently enacted U.S. Public Law 110-85 (also known as H.R. 3580, or Food and Drug Administration Amendments Act of 2007), Title VIII, Section 801 mandates the expansion of ClinicalTrials.gov. Specific implications for the Protocol Registration and Results System (PRS) include:
6. Several data elements that were previously optional will become required. Generally these elements were already required by ICMJE/WHO policies.
7. A small number of data elements have been added to facilitate full compliance with the new law and to support coreClinicalTrials.gov operations.
8. Certain device trials that relate to unapproved or un-cleared devices, will not be posted until the device is approved or cleared by the FDA. Note that the requirements for registering such trials (e.g., time of initial registration, required data elements) are not affected by this provision.
9. By law, the additional information was required as of December 26, 2007 (90 days after enactment of the law) for certain trials. Registrants are advised to provide the revised set of data elements for new registrations and active studies. Studies that were completed prior to enactment (September 27, 2007) are not subject to the new registration rules, but may be updated at the discretion of the registrant.
10. CAUTION: It is your responsibility to ensure that your registration meets the requirements of applicable laws and regulations. Acceptance by the PRS and assignment of an NCT number to a protocol record does not ensure full compliance with all applicable laws.
11. The mechanism for delaying full publication of applicable device trials is now in place. Sponsors of such trials can now release the associated protocol records. Details of the protocol will not appear on ClinicalTrials.gov until after Delayed Posting is set to "No" by the registrant and the record is re-released.
12. NIH Guidance:

<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-014.html>.

[**http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-147.html**](http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-147.html)**.**

[**http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-007.html**](http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-007.html)**.**

1. OHRP Guidance:

[**http://www.hhs.gov/ohrp/international/clinical-trial-registries/**](http://www.hhs.gov/ohrp/international/clinical-trial-registries/)**.**

[**http://www.hhs.gov/ohrp/international/compilation-human-research-standards/**](http://www.hhs.gov/ohrp/international/compilation-human-research-standards/)**.**