



**Procedure Name:** Site Listing on [ClinicalTrials.gov](http://ClinicalTrials.gov)  
**Effective Date:** April 7, 2010  
**Revision:** 02  
**Initiating Department:** Office of Clinical Trials  
**Procedure Number:** CR-009, Rev 2  
**Application:** Office of Clinical Trials  
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**OBJECTIVE:**

Ensure that sponsors list trials conducted at UNTHSC-FW under the *Contacts and Locations* section of the study-specific tab on the National Institute of Health’s (NIH) “ClinicalTrials.gov” website.

**REFERENCES:**

Guidance Document	Guidance on New Law (Public Law 110-85) Enacted to Expand the Scope of ClinicalTrials.gov: Registration Visit <a href="http://prsinfo.clinicaltrials.gov/fdaaa.html">http://prsinfo.clinicaltrials.gov/fdaaa.html</a>
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**SCOPE:**

Public Law 110-85, enacted in September 27, 2007 requires that “applicable trials” be registered on the NIH’s website, “[ClinicalTrials.gov](http://ClinicalTrials.gov)”. Under the statute, these trials generally include:

- Trials of Drugs and Biologics: Controlled, clinical investigations, other than Phase 1 investigations, of a product subject to FDA regulation;
- Trials of Devices: Controlled trials with health outcomes of a product subject to FDA regulation (other than small feasibility studies) and pediatric post-market surveillance studies.

**RESPONSIBILITY:**

For clinical trials, the sponsor of the trial (as defined in 21CFR 50.3) is responsible for complying with the requirement to register the trial. The Principal Investigator (PI) or if delegated, the Study Coordinator is responsible for corresponding with the sponsor to ensure that the sponsor includes the UNTHSC-FW site location under the *Contacts and Locations* section of the study-specific tab on “[ClinicalTrials.gov](http://ClinicalTrials.gov)”. If the sponsor declines to include the UNTHSC-FW site, the PI or designee will notify the Office of Clinical Trials.

For Investigator-Initiated clinical trials that do not involve FDA drugs, biologics or devices as described above, the trial is not required by law to be listed on ClinicalTrials.gov; however, the investigator nonetheless may wish to register the trial and should do so through the Office

of Clinical Trials (UNTHSC-FW) only after having obtained UNTHSC IRB approval for that trial.

**REVISION HISTORY**

<b>Rev</b>	<b>DCO</b>	<b>Description of Change</b>	<b>Approved by</b>
2	08-016	Paragraph regarding Investigator-Initiated trials added; website added to References	Michael V.W. Bergamini

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