ClinicalTrials.gov
Escalation and Enforcement Procedure

This policy applies to Principal Investigators of investigator-initiated, Emory-Sponsored clinical trials registered in ClinicalTrials.gov where the PI is the IND or IDE holder, the clinical trial follows the NIH policy for ClinicalTrials.gov, and/or the study meets the criteria for International Committee of Medical Journal Editors (ICMJE) requirements.

Statement of the Problem:

- Adherence to ClinicalTrials.gov is important since federal regulations set forth by the Food and Drug Administration and policies set forth by the National Institutes of Health are now in place to ensure registration and results reporting in ClinicalTrials.gov, as well as the timeliness of updates to the system.
- Penalties for ClinicalTrials.gov are strict and explicitly defined – including penalties up to $10,000 per day for violations, criminal prosecution, withholding of NIH funding to the Investigator and/or the institution, public identification of non-compliant study records on the ClinicalTrials.gov website, and an inability to publish.
- Delays of updates to the website or lack of review and response by Investigators in regards to potential ClinicalTrials.gov problems/errors may occur despite several messages to department/division contacts requesting updates and verification of ClinicalTrials.gov records.
- Several barriers have been identified in regards to information availability and also timeliness of the required updates in ClinicalTrials.gov. These include lack of easy access to some data elements required for quick turnaround in ClinicalTrials.gov, the ClinicalTrials.gov system not being user-friendly or intuitive, heavy workloads with competing priorities for investigators, and PI lack of knowledge of the timelines and their importance for ClinicalTrials.gov registration, updates, and results reporting.

ClinicalTrials.gov Assessment and Corrective Action:

- All PIs and record owners will be informed that they are responsible for ensuring timely responses to requests and updates. The updates may be appropriately delegated; however, the responsibility for releasing and reviewing the study record in ClinicalTrials.gov may not.
    1) Timely response is defined as within three business days. If no response is received within three business days, a second request will be sent and the procedures for Escalation and Enforcement will ensue.
    2) Upon the 2nd email request, OCR will send a notice to the PI and CRC with a copy of this policy and a request for the PI to address the ClinicalTrials.gov questions and/or verification within two business days.
    3) If the issue is not resolved and/or no response is received, OCR will send a notice to the PI and CRC, copying the Department Chair and Division Director, requesting a written explanation of why the issues persist in ClinicalTrials.gov and/or why the information is not updated. If no response is received within 30 days, or an unsatisfactory response is received, then the Associate Dean for Clinical Research will contact the PI.
    4) If problems continue or the lack of responsiveness continues, the Associate Dean for Clinical Research will send an email to the Department Chair noting the continuing issue and asking him/her to intervene with the PI to promptly resolve the problem. If problems are not resolved in an expeditious manner, an invitation will be extended to the next Clinical Trials Executive Committee meeting, and may require the study to be put on hold. If subsequent occurrences and/or non-responsiveness occurs, the matter will be referred to the Clinical Trials Executive Committee and the Department Chair to determine if the PI needs to be removed from the study and if any further action is necessary.