EMORY UNIVERSITY | Office for Clinical Research
Research Administration

To: Principal Investigators and Research Coordinators

From: Jeffrey L. Lennox, MD, Associate Dean for Clinical Research, School of Medicine
David L. Wynes, PhD, Vice President of Research Administration, Emory University

Re: New Requirements for ClinicalTrials.gov

Date: March 29, 2017

A revised FDA Final Rule and NIH Policy on Clinical Trials Registration and Results Information Submission became effective on January 18, 2017. These requirements apply to Principal Investigator (PI)-initiated clinical trials where Emory is considered the sponsor. The NIH also issued a companion policy requiring that language on the dissemination of clinical trial information be included in new or competing applications submitted on or after January 18, 2017. The FDA and NIH have established strict timelines for updating ClinicalTrials.gov and have incorporated heavy penalties for failing to meet these timelines.

The additional workload for these requirements is significant and places new responsibilities on PIs. To ensure that PI-initiated studies are in compliance, Emory has established a ClinicalTrials.gov Service Center. For all awards issued on or after September 1, 2017, the service center in OCR will manage all PI-initiated studies where Emory is considered the sponsor.

The NIH allows direct charging the costs of complying with the new clinical trial reporting requirements and at Emory such studies will be charged a fee of $3,500. This amount reflects the work necessary to comply throughout the life of the study and is not the full cost since the service center is being subsidized by the institution.

This service center fee needs to be incorporated in the budget as a direct charge covering the support needed to facilitate the registration, periodic updates, and results reporting within ClinicalTrials.gov for the duration of the study. The PI will continue to review the accuracy of the information entered by the service center and document their approval in ClinicalTrials.gov.

Template language for the dissemination of clinical trial information and the ClinicalTrials.gov Service Center fee are now available on OCR's website at www.ocr.emory.edu/ct.gov/language.html. If you have any questions, please contact OCR@emory.edu.

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NIH Grant Application & Progress Report Template Language for Adherence to ClinicalTrials.gov Requirements

New Competing Clinical Trials:

(New applications submitted on or after January 18, 2017)

ClinicalTrials.gov *(must include this heading)*

The proposed project will require registration in ClinicalTrials.gov. Registration information will be submitted within 21 days of enrollment of the first subject and summary results information will be reported within one year of the primary completion date.

(Add to the Budget Justification section for new or competing applications submitted on or after January 18, 2017)

ClinicalTrials.gov ($3,500)

$3500 is requested for the support needed to facilitate the registration, periodic updates, and results reporting within ClinicalTrials.gov for the duration of the study.

Progress Reports on NIH Clinical Trials:

(New or competing applications submitted on or after January 18, 2017)

ClinicalTrials.gov *(must include this heading)*

The following project is registered in ClinicalTrials.gov: *Insert ClinicalTrials.gov registry number (NCT#), the brief title listed in ClinicalTrials.gov, and the responsible party's name, organization, and email address.*