LAWRENCE UNIVERSITY POLICY ON THE DISSEMINATION OF NIH-FUNDED CLINICAL TRIAL INFORMATION ON CLINICALTRIALS.GOV

Purpose

This policy is intended to ensure that NIH-funded clinical trials registration and results reporting to ClinicalTrials.gov at Lawrence occur in compliance with NIH policy requirements. ClinicalTrials.gov is a registry of federally and privately supported clinical research maintained by the National Library of Medicine (NLM) and the National Institutes of Health (NIH). The registry provides easy access to information about a wide range of studies and is aimed at increasing transparency and improving public awareness of research in support of public health.

Regulatory Background

Title VIII of the Food and Drug Administration Amendment Act of 2007 (FDAAA) established legal requirements for sponsors and designated principal investigators responsible for certain clinical trials to register and report results information to ClinicalTrials.gov.

To comply with FDAAA, the National Institutes of Health (NIH) issued regulation at 42 CFR, Part 11, on September 21st, 2016, to establish the expectation that all investigators conducting clinical trials funded in whole or in part by NIH will ensure that these trials are registered and results information is submitted to ClinicalTrials.gov. This regulation was effective January 18, 2017.

Applicable Clinical Trials

This policy applies to all NIH-funded clinical trials, whether funded in whole or in part by the NIH and regardless of study phase or type of intervention. NIH defines "clinical trial" as a *research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes. This definition encompasses phase 1 trials of FDA-regulated drug and biological products, small feasibility studies of FDA-regulated device products, and studies of any intervention not regulated by the FDA, e.g., behavioral interventions.*

Responsible Party

As authorized in 42 CFR 11.10, Lawrence designates the Principal Investigator (PI) as the responsible party for registering and reporting trials, so long as the principal investigator is responsible for conducting the trial, has access to and control over the data from the clinical trial, has the right to publish the results of the trial, and has the ability to meet all of the requirements for the submission and updating of clinical trial information.

The office of Corporate, Foundation, and Sponsored Research Support (CFSR) will obtain written acknowledgement from the PI of their responsibilities as the Responsible Party before the grant period starts. The PI will work with CFSR to notify the appropriate NIH Director as needed.

PIs who leave employment at Lawrence in the midst of an NIH-funded clinical trial will be responsible for facilitating the transfer of clinical trial sponsorship to their new institution. If no entity at Lawrence is designated the responsible party on the NIH-funded clinical trial (e.g. participating as a subawardee), CFSR and the investigator will coordinate with the responsible party to ensure compliance with all regulatory requirements.

In the event that a PI who has been designated the responsible party no longer meets or is no longer able to meet all the requirements for being so designated, the sponsor must withdraw the

designation in the format specified at https://prsinfo.clinicaltrials.gov, at which time the sponsor will be considered the responsible party unless and until the sponsor makes a new designation.

Responsibilities

CFSR will be responsible for

- Establishing and maintaining an organizational account with ClinicalTrials.gov.
- Working with the PI to provide NIH a dissemination plan as needed.
- Obtaining acknowledgment of the PI's understanding of responsibility in support of an applicable clinical trial before the grant period starts.
- Helping facilitate the PI's dissemination of study results through ClinicalTrials.gov registration and reporting.

The PI will be responsible for the following:

- Applicants seeking NIH funding will be required to submit a plan for the dissemination of NIH-funded clinical trial information.
- The PI will obtain IRB approval prior to the registration of a study in ClinicalTrials.gov.
- The PI will register the clinical trial and report the results information on ClinicalTrials.gov as outlined in the NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information.
- Once a record is established on ClinicalTrials.gov, the PI will update and maintain accurate records and resolve any problems that arise.
- The PI will include a specific statement relating to the clinical trial information published at ClinicalTrials.gov in the informed consent documents for all clinical trials.
- The PI will complete Adverse Events reporting at the conclusion of the project as required.

Deadlines

Applicable clinical trials are required to be registered in ClinicalTrials.gov not later than 21 calendar days after the enrollment of the first participant. Lawrence strongly encourages PIs to register the trial prior to enrolling the first subject. Results information from those trials must be submitted not later than one year after the trial's primary completion date. Submission of results information can be delayed in certain circumstances for up to two additional years for trials of products regulated by the FDA that are unapproved, unlicensed, or uncleared or for trials of products for which approval, licensure, or clearance of a new use is being sought. If the PI requires such a waiver, they will work with CFSR as soon as known to obtain permission from NIH.

Compliance and Enforcement

Lawrence will withhold IRB approval for any study under a noncompliant principal investigator. Compliance with the NIH policy can be considered in future funding decisions and will be part of the terms and conditions to accept a funding award from the NIH. Failure to comply will result in enforcement action, including suspension or termination of the award or contract. It may also prevent publication in International Committee of Medical Journal Editors (ICMJE) journals. Noncompliant records may be identified on ClinicalTrials.gov. A responsible party who submits false and/or misleading information is subject to civil monetary penalties and/or other civil or criminal remedies available under U.S. law.