1. Purpose

The purpose of this SOP is to:

a. Document that Faculty in the Perelman School of Medicine (PSOM) are required to comply with the NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information [https://grants.nih.gov/policy/clinical-trials/reporting/understanding.nih-policy.htm](https://grants.nih.gov/policy/clinical-trials/reporting/understanding.nih-policy.htm) (NIH policy); and

b. Provide guidance regarding submission of and compliance with dissemination plans required to be submitted to NIH in proposals for funding for clinical trials (Dissemination Plans).

2. Scope

This SOP applies to PSOM Faculty who submit applications for NIH funding for clinical trials (Applicants) and also to those PSOM Faculty obligated to comply with Dissemination Plans included in NIH grant applications (Applications).

The NIH definition of clinical trial is:

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 (Clinical Trial).¹

¹ The definition of Clinical Trial for NIH purposes requires for NIH-funded trials registration and reporting on clinicaltrials.gov of a broader category of studies than had previously been subject to the clinicaltrials.gov registration and reporting requirements. For information regarding requirements for registration and reporting of clinical trials that are not NIH-funded, please see: What is ClinicalTrials.gov and why do I need to register my study? at: [https://www.research.upt.edu/ocr/clinical-trials-gov.html](https://www.research.upt.edu/ocr/clinical-trials-gov.html)
3. Instructions

a. PSOM Faculty seeking NIH funding for a Clinical Trial via a competing application or contract proposal are required to submit a Dissemination Plan to address how the expectations of NIH policy will be met. The Dissemination Plan will be attached to the grant application and must contain sufficient information to assure the following:

i. The Applicant will ensure that clinical trials under the award are registered and results information is submitted to ClinicalTrials.gov as outlined in the NIH policy and according to the specific timelines stated in the policy.

ii. Informed Consent documents for the Clinical Trial(s) will include a specific statement relating to posting of clinical trial information at ClinicalTrials.gov

iii. The recipient institution has an internal policy in place to ensure that Clinical Trials registration and results reporting occur in compliance with policy requirements. This SOP may be used to document PSOM policy.

b. The Applicant and others covered by the Dissemination Plan must comply with the Dissemination Plan. Generally within PSOM, the Principal Investigator is responsible for registering the trial and submitting the results.

4. Procedures

Comprehensive information relating to registration and management of information required to be submitted on clinicaltrials.gov may be found at: https://www.med.upenn.edu/ocr/clinical-trials.gov.html

5. References
