Harvard Pilgrim Health Care, Inc.
Harvard Pilgrim Health Care Institute, LLC
Office of Sponsored Programs

Policy and Procedure

TITLE: Dissemination of Information from NIH-Funded Clinical Trials

---

PURPOSE:
To provide guidance to the Harvard Pilgrim Health Care, Inc. (HPHC) and Harvard Pilgrim Health Care Institute, LLC (HPHCI) (collectively, HPHC/I) research community for compliance with the National Institutes of Health (NIH) expectation that all NIH-funded awardees and investigators conducting clinical trials will register and report results of their trial on Clinicaltrials.gov, as described in the "NIH Policy on Dissemination of NIH-Funded Clinical Trial Information" in NOT-OD-16-149.

PERSONS AFFECTED:
This policy & procedure (P/P) applies to all HPHC/I NIH-funded investigators conducting clinical trials.

POLICY:
HPHC/I NIH-funded investigators must certify their compliance with the NIH Policy in all grant and cooperative agreement submissions, contract proposals, and progress reports for clinical trials in which HPHC is the prime recipient. Submissions and contract proposals must include an explanation of how the requirements of the NIH Policy will be met by HPHC/I.

When HPHC is the prime recipient, the HPHC/I principal investigator is the responsible party, unless otherwise designated by the clinical trial's sponsor. As the responsible party, the HPHC/I principal investigator must (1) register all clinical trials funded by NIH at ClinicalTrials.gov within 21 days of the enrollment of the first subject, (2) update the information at ClinicalTrials.gov at least every twelve months, and (3) enter summary results into ClinicalTrials.gov within one year of the clinical trial completion date.

Finally, per 21 CFR 50.25(c), all informed consent documents for any clinical trials funded by the NIH must include the following statement: "A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time."

The HPHC/I Office of Sponsored Programs (OSP) is responsible for monitoring compliance with these requirements. Failure of the HPHC/I Principal Investigator to comply with these policies may result in the suspension the project.

DEFINITIONS:

Applicable Clinical Trial: "Applicable clinical trial is the term used in Title VIII of the Food and Drug Administration Amendments Act (FDAAA) of 2007 (P.L. 110-85) to designate the scope of clinical trials that may be subject to the registration and results reporting requirements in FDAAA" (Glossary of NIH Terms, https://grants.nih.gov/grants/glossary.htm#A, retrieved 11 May 2020).

Clinical Trial: "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" (Glossary of NIH Terms, https://grants.nih.gov/grants/glossary.htm#C, retrieved 11 May 2020).

Responsible Party: For applicable clinical trials, this may be either "the sponsor of the clinical trial, as defined in 21 CFR 50.3" or "the principal investigator (PI) of such clinical trial if so designated by a sponsor, grantee, contractor, or awardee, so long as the PI 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 of clinical trial information" (FDAAA 801 and the Final Rule, https://clinicaltrials.gov/ct2/manage-recs/fdaaa#WhoIsResponsibleForRegistering, retrieved 15 June 2020). For other clinical trials, "the awardee or investigator will be responsible for carrying out the tasks and meeting the timelines described in regulation" (Notice Number NOT-OD-16-149, NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information, https://grants.nih.gov/grants/guide/notice-files/not-od-16-149.html, retrieved 15 June 2020). Every clinical trial must have a responsible party designated for the purposes of registering a clinical trial and reporting results through ClinicalTrials.gov. In order to avoid duplicate registrations, a clinical trial may only have one responsible party.

PROCEDURE:

A Protocol Registration and Results System (PRS) account associated with HPHC is required for reporting in ClinicalTrials.gov. If the HPHC/I principal investigator or designee does not have a PRS account, the HPHC/I principal investigator or designee should e-mail the Director of OSP to request that one be created.

Effective Date: 8/20/2020	**Owner: Director, Office of Sponsored Programs**
Reviewed By/On: A. Cabell, N. Mulherin, C. Johnson 8/20/2020	
Replaces P/P Dated: NA	
Related Documents: NOT-OD-16-149, NIH Policy on Dissemination of NIH-Funded Clinical Trial Information, https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-149.html Dissemination Plan instructions, G.500 PHS Human Subjects and Clinical Trials Information, General Application Guide for NIH and Other PHS Agencies (Forms F), https://grants.nih.gov/grants/how-to-apply-application-guide/forms-f/general/g.500-phs-human-subjects-and-clinical-trials-information.htm#4.7	
Approved By:	