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To: Principal Investigators Conducting Clinical Trials
From: Pamela Caudill, Senior Associate Provost for Research Administration
Re: ClinicalTrials.gov Registration and Reporting Requirements

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The National Institutes of Health (NIH) announced its Policy on the "Dissemination of NIH-Funded Clinical Trial Information" (Notice Number: NOT-OD-16-149) and the Department of Health and Human Services (DHHS) issued complementary requirements in the Clinical Trial Registration and Results Information Submission Regulation located at 42 CFR Part 11. The regulation and the policy address the researcher's obligation to register and submit results to ClinicalTrials.gov. The effective date of the NIH policy and the Regulation is January 18, 2017. Some of the significant changes under the new Final Rule & NIH Policy include the following:

- NIH requires that all NIH-funded awardees and investigators conducting clinical trials, funded in whole or in part by the NIH, ensure that:
    - All clinical trial proposals or applications include a plan for the dissemination of NIH-funded clinical trial information that will address how the expectations of the Policy will be met;
    - All NIH-funded clinical trials regardless of study phase, type of intervention, or whether they are subject to the Regulation are registered (including trials involving only behavioral interventions); and
    - Clinical trial summary results information is submitted to ClinicalTrials.gov for public posting.

- All Applicable Clinical Trials subject to the Regulation must be registered no later than 21 days after enrolling the first human subject participating in any of the following clinical trials:
    - Interventional biological, drug, and device products regulated by the Food and Drug Administration (FDA) (except phase 1 trials of drug and biological products and small feasibility studies of device product); and
    - Pediatric post-market surveillance study of a device product required by the FDA.
- More frequent updating of data elements is required.

- The data elements required for registration and reporting have expanded.
- Penalties for failing to properly register and report include financial penalties and the withholding of DHHS and NIH grant funds.

Clinical Trial registration is expected to occur prior to the enrollment of the first study subject. Failure to do so will restrict publication in journals that follow International Committee of Medical Journal Editors (ICMJE) requirements. Researchers should be aware of other registration requirements imposed by a sponsor and/or journals.

The Centers for Medicare and Medicaid Services (CMS) requires registration of Qualifying Trials before claims are submitted to Medicare. If a clinical trial does not qualify, then the costs for all items and services related to the clinical trial cannot be billed to Medicare.

To assist in better understanding of the ClinicalTrials.gov registration and reporting requirements, please refer to **HRPP Policy 1000, *Clinical Trial Registration and Results Reporting Requirements***. The policy includes a Reference section and Attachment 1 with Frequently Asked Questions.

Principal Investigators may contact the Yale Center for Clinical Investigation (YCCI) for assistance with ClinicalTrial.gov registration and reporting. For more information, please CLICK HERE or visit the HRPP ClinicalTrials.gov Support webpage.

Principal Investigators who are unsure as to whether a clinical trial is subject to ClinicalTrial.gov disclosure requirements should contact Yale.CTgov@yale.edu or HRPP@yale.edu for assistance.