ClinicalTrials.gov

Workshop

Date: Wednesday, December 14, 2016

Time: Noon – 1:30 PM

Location: Johns Hopkins University School of Nursing, Room 202

Speakers: Dr. Nidhi Atri, M.D. and Anthony Keyes, MBA, PMP

RSVP: SON-Innovation@jhu.edu

Topics

Speakers will cover features of ClinicalTrials.gov, which will include topics ranging from overview and background to registration and reporting of results for clinical trials. As investigators, the primary website used is register.clinicaltrials.gov. Accounts are set up through this Protocol Registration and Results System (PRS), by the PRS Administrators for each Johns Hopkins Entity, JHU SOM (which encompasses the SON), The Sidney Kimmel Comprehensive Cancer Center (SKCCC), and JHU Bloomberg School of Public Health. Nidhi and Tony are the PRS Administrators for JHU SOM and are available to provide assistance with study maintenance or any other assistance you may require in navigating the website or entering results. Investigators without an account and unfamiliar with the website, can receive assistance with creating an account and register a study.

CT.gov Program

This program was created not only to regulate compliance of investigators with registration and results reporting, but to also serve as a resource for investigators. Previously, registration was limited to "Applicable Clinical Trials" (ACT), meeting criteria set forth by a handful of governing agencies; such as, U.S. Congress via the Food and Drug Administration Amendments Act (FDAAA), the National Institutes of Health (NIH), The World Health Organization (WHO), Centers for Medicare & Medicaid Services (CMS), and The International Committee of Medical Journal Editors (ICMJE).

Program Update

On September 16th, The U.S. Department of Health and Human Services (HHS) released the Final Rule to addresses in detail, the requirements for submitting registration results information to ClinicalTrials.gov. The National Institute of Health (NIH) also released a Complementary Policy for registration and results submission to ClinicalTrials.gov **for all NIH-funded trials**, including those which may not be covered by the Final Rule. These policies go in to effect on January 18th, 2017 and the NIH policy alone dictates the registration of several more studies, which historically did not require registration. Furthermore, according to FDAAA, an organization can be fined $10,000 per day for each study with results which have not been reported. Investigators are given one full year after their primary completion date to report these results prior to becoming flagged with "late results per FDAAA" status, yet the number of late results at Johns Hopkins School of Medicine alone are daunting. Should researchers have a study which falls under this category, they can schedule a one-on-one appointment should they need assistance.