ClinicalTrials.gov

This guide has been created for Principal Investigators and study teams to effectively use ClinicalTrials.gov

1. CREATE AN ACCOUNT

   Contact the appropriate Protocol Reporting System (PRS) Administrator
   Oncology (SKCCC) – Monica Owens (carltmo@jhmi.edu)
   JHSPH – Miye Schakne (mschakne@jhsph.edu)
   JohnsHopkinsU (SOM, SON) – Anthony Keyes (akeyes1@jhmi.edu)

2. REGISTRATION

   Ensure you have an Applicable Clinical Trial (ACT) which requires registration
   Log-on to PRS: https://register.clinicaltrials.gov/
   Enter the required and optional data elements
   Assign the “Sponsor” (Johns Hopkins University) as the Responsible Party (RP)
   Check for spelling and to see that all acronyms are expanded using the “Spelling” feature
   Check for any “Errors” or “Warnings”
   Have the RP approve and release the record for review by a ClinicalTrials.gov PRS Reviewer
   Submit a complete and timely response to any comments from the ClinicalTrials.gov PRS Reviewer

3. RESULTS REPORTING

   Ensure you have an Applicable Clinical Trial (ACT) which requires results reporting
   Start preparing early as results reporting can be a time-consuming and rigid process
   Enter the required and optional data elements and submit prior to the 12-month timeline
   Contact registerclinicaltrials@jhmi.edu for statistical support or any questions

4. TIPS, TRICKS AND TIMELINES

   ICMJE requires trial registry at or before first patient enrollment as a condition for publication
   Set calendar reminders:
     Records must be updated every 6 months
     If Overall Recruitment Status or completion date changes, then update record within 30 days
     Enter and submit basic results no later than 12 months after the Primary Completion Date
   Contact registerclinicaltrials@jhmi.edu if the PI leaves the institution
   Contact registerclinicaltrials@jhmi.edu with any questions