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

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