1. PURPOSE
   1. This policy establishes the process to ensure required Clinical Trials are registered and remain in compliance with ClinicalTrials.gov, per their policies and requirements.
2. REVISIONS FROM PREVIOUS VERSION
   1. None
3. POLICY
   1. For investigator-initiated studies, Clinical Trials required to register at [www.ClinicalTrials.gov](http://www.ClinicalTrials.gov) will not receive final approval until proof of registration is provided.
      1. Clinical Trials that are out of compliance with updating or reporting results may not receive approval at the time of continuing review until proof that the record has been updated and released to the public site is provided.
      2. If a Principal Investigator is leaving the University of Maryland Baltimore, modifications submitted to have another investigator assume Principal Investigator responsibilities or closure reports may not receive approval until proof that the Responsible Party has been updated has been provided.
   2. Sponsors and Principal Investigators are responsible for registering applicable clinical studies with ClinicalTrials.gov. This is done in the ClinicalTrials.gov Protocol Registration and Results System (PRS).
   3. Section 801 of the Food and Drug Administration Amendments Act (FDAAA 801) requires Responsible Parties to register and submit summary results of Clinical Trials with ClinicalTrials.gov.
      1. Registration is required for trials that meet the FDAAA 801 definition of an "applicable clinical trial" and were either initiated after September 27, 2007, or initiated on or before that date and were still ongoing as of December 26, 2007. Applicable Clinical Trials include the following:
         1. Trials of drugs and biologics: Controlled clinical investigations, other than phase 1 clinical investigations, of drugs or biological products subject to Food and Drug Administration (FDA) regulation
         2. Trials of devices: Controlled trials with health outcomes of devices subject to FDA regulation, other than small feasibility studies, and pediatric post-market surveillance required by FDA

3.4 The [National Institutes of Health (NIH) Policy on Dissemination of NIH-funded Clinical Trial](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-149.html) [Information](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-149.html) applies to all NIH-funded clinical trials regardless of study phase, type of intervention, or whether they are subject to the Clinical Trial Registration and Results Information Submission regulation at 42 CFR Part 11.

1. RESPONSIBILITIES
   1. Registration and maintenance of the ClinicalTrials.gov site is the shared responsibility of Clinical Trial Investigators/Sponsors, Research Institution/Organization and ClinicalTrials.gov team.
      1. **PRS Users** enter information about their clinical trials, ensuring that the information is correct, readily understood by members of the public, and updated in a timely manner.
      2. **PRS Administrators** are responsible for the process by which clinical trial information is released to ClinicalTrials.gov on behalf of their organization. This process includes ensuring protocols are kept up to date and creating, maintaining, and disabling accounts for PRS users
         1. HRPO is the PRS administrator for protocols registered by Principal Investigators when University of Maryland Baltimore is the “sponsor.”
      3. The **ClinicalTrials.gov Team** maintains the PRS and the ClinicalTrials.gov site and may make minor corrections to records.
2. PROCEDURE
   1. PRS User accounts are created, maintained, enabled and disabled by the PRS Administrator.
      1. Principal Investigators require a PRS User account to be listed as the Responsible Party of a study. If an account is needed, the Principal Investigator can request one by contacting [hrpo@umaryland.edu](mailto:hrpo@umaryland.edu).
      2. The PRS administrator has the ability to change the ownership of the ClinicalTrials.gov record, as necessary.
   2. An applicable clinical trial is entered by the PRS User using the Protocol Registration System (PRS).
      1. The University of Maryland is the Sponsor of any UMB investigator-initiated studies.
      2. The Responsible Party is the protocol Principal Investigator as identified in CICERO.
   3. Once a protocol record has been published on ClinicalTrials.gov, it remains in the system even after a trial has closed and cannot be deleted.
   4. Records released to the public website are required to be updated periodically depending on the protocol’s recruitment status.
      1. Recruiting records require updates every six months.
      2. Non-recruiting records require annual updates.
      3. Responsible Parties should update their records within 30 days of a change to:
         1. Recruitment status;
         2. Overall Recruitment status; or
         3. Completion Date
      4. Results generally must be submitted not later than one year after the trial’s primary completion date.
   5. After a protocol has been entered or updated and marked Complete, it must be Approved and Released by a PRS Administrator.
      1. If the Investigator is designated as the Responsible Party for a study, that individual has the authority and responsibility to Approve and Release the record, even if not a PRS Administrator.
   6. The PRS Administrator has the overall responsibility to ensure that the organization’s records are verified, updated, and re-released as needed, or at least every six months.
      1. The PRS Administrator is responsible for following up on problem records on a weekly basis.
         1. Log in to the registration site.
         2. Select “Problems: UMaryland Records”
         3. Follow up with Principal Investigators as necessary.
      2. The PRS sends an automatic email notification when a protocol is entered or modified in the registration database. These notifications are addressed to [hrpo@umaryland.edu](mailto:hrpo@umaryland.edu) and can be used to assess the ongoing activity of protocols.
         1. The PRS Administrator is responsible for following up on these emails on a weekly basis.
      3. Notifications should be addressed to the Principal Investigator. All communication should be sent via the Contact Study Team function in the CICERO main protocol workspace.
      4. If the Principal Investigator has not complied within 2 weeks, a second notice should be sent via CICERO re-affirming this requirement. Use wording similar to the initial notification and add within 2 weeks compliance requirement.
      5. If the site is non-compliant with the deadline given in the second notice, notify a Director, as failure to comply with registering a new protocol or updating a registered protocol in the time specified in the second notice may result in suspension of IRB approval of the protocol.
3. MATERIALS
   1. CICERO
   2. SOP: Definitions
   3. SOP: IRB Records
   4. Operations Manual
4. REFERENCES
   1. ClinicalTrials.gov
   2. Grants.nih.gov