

Reference for Creating a Clinical Trials.gov Record

The Clinical Trials.gov record is for the public and as such the information needs to be in terms that the public can understand. If medical terms or acronyms are used, please explain the first time it is used. Please use appropriate level of comprehension, similar to that in an informed consent document. Refer to <http://humansubjects.stanford.edu/general/glossary.html> for lay terms.

Clinical Trials required to register will not receive final approval until proof of registration is provided.

Failure to comply with updating records may result in delay in Continuing Review approvals or suspension of IRB approval.

See the Clinical Trials.gov Main Menu (once logged in) for complete instructions and helpful hints for completing the record.

- ❖ To login, go to <http://register.clinicaltrials.gov>
- ❖ Complete the three fields on the Login screen:
 - o Organization: **UMaryland**
 - o Username: user login name
 - o Password: (case-sensitive)
- ❖ To create a new record, click “Create” on the Main Menu. Continue through the record, completing each section.
 - o Whoever creates the record is considered the “Owner.”
 - For others to be able to view and edit the record, the “Owner” must give access via the “Access List” link at the top of the record.
 - The “Owner” is the only party who is able to grant access to the record.
 - Contact HRPO (hrpo@umaryland.edu) for assistance in changing the “Owner,” if necessary.
 - o Select “Definitions” at the top of each screen to obtain descriptions of each field.
 - o The Unique Protocol ID is the CICERO application number (HP-000xxxxx).
 - o The University of Maryland is the Sponsor of any UMB investigator-initiated studies.
 - o The Responsible Party is the protocol **Principal Investigator** as identified in CICERO.
 - **The person designated on the CT.gov record as the Responsible Party must ensure that the record is complete and accurately reflects the protocol information as approved by the IRB.**
 - The Principal Investigator must have an individual CT.gov account to be listed as the Responsible Party.
 - Contact HRPO (hrpo@umaryland.edu) for new CT.gov accounts.

- o Oversight information should be entered verbatim as follows:
 - Board Name: U of Maryland, Baltimore, Professional Schools IRB
 - Board Affiliation: U of Maryland Baltimore
 - Business Phone: 410-706-5037
 - Business Email: hrpo@umaryland.edu
 - Business Address: Human Research Protections Office, 620 W. Lexington Street, 2nd floor, Baltimore, MD 21201
- o Once you have completed all required sections, review any Errors, Warnings or Notes and make changes as needed.
 - **ERROR messages indicate serious issues that must be addressed.**
 - **WARNING messages indicate potentially serious issues that should be reviewed and addressed as needed.**
 - **NOTE messages indicate potential issues that should be reviewed and addressed as needed.**
- ❖ Select “Preview” to see a rough approximation of how the record will appear on CT.gov.
- ❖ Select “Record Summary” to see the next steps for finishing the record submission process.
 - o Protocols are “In Progress” while initial data entry or an update is ongoing.
 - o Select “Entry Complete” when the record is ready for internal review.
 - o The Responsible Party for a record (the study PI) selects “Approved” when the record has passed internal review.
 - o The Responsible Party then selects “Released” to submit the record to ClinicalTrials.gov.
 - The HRPO is the PRS Administrator for University of Maryland, Baltimore. **The HRPO does not approve or release records.** When the Investigator is designated as Responsible Party for a study, that individual has the authority (and responsibility) to Approve and Release the record
 - o If questions arise during CT.gov administrative review, CT.gov will email the Responsible Party and record owner.
- ❖ Records are required to be updated:
 - o Within 30 days of a change to Recruitment Status or Completion Date
 - o Every 6 months, if Recruiting
 - o Every 12 months, if Not Recruiting
 - o Results must generally be submitted not later than one year after the trial’s primary completion date.
 - At each update, the record returns to “In Progress.”
 - After each update, the Responsible Party must again Approve and Release the record.
- ❖ Study results must be posted in the CT.gov record once data is available for at least one Primary Outcome Measure (as listed in the Outcome Measures section of the CT.gov record).