Creating a New Study Record – Field Requirements

1. Go to Website: https://register.clinicaltrials.gov
2. Log-in Using Organization Name: OhioU

3. Under Protocol records select Create

4. **Unique Protocol ID:** refers to the OSU IRB number ex:2014H0112, Please answer all remaining questions in this section as applicable to your study.

5. Complete all section by Clicking the **Edit** button to the left of each section.
   Under the Responsible Party tab select **Sponsor-Investigator** for Investigator Initiated trials.

6. Under Review Board enter contact information as listed in screen clip below
7. **Record Verification Date:** this date refers to current month and year. When updating a record always update the Record Verification Date.

8. Complete Record by selecting Edit next to each section, add information as appropriate to your study.

9. Verify Your record is free from errors prior to completing

Warning messages on the **Edit Protocol Record** screen may be present to identify possible problems as follows:

- **ERROR** messages indicate serious problems that need to be addressed.
- **ALERT** messages indicate problems that need to be addressed.
- **NOTE** messages indicate potential problems that should be reviewed and corrected as needed.

10. Once your record has been updated, select **Completed** then the Administrator will review and Approve and PI will need to Release.

    In Progress | Completed | Approved | Released

11. Confirm the Principle Investigator (PI) has been added to the access list, if he or she is not the Owner. Finally mark the record as **completed**, then the Administrator will Approve and the PI should Release.

12. Note: Once a record is released to ClinicalTrials.gov it will then be reviewed by ClinicalTrials.gov. If errors exist the record will not be accepted. The PRS system will notify the Owner and Responsible Party if a problem exists. Problems can be viewed by selecting the Problems tab located at the top of the record. Specific QA Review comments can be viewed by clicking on QA Review Comments.

13. If a protocol returns with QA review comments, address comments and repeat release process.

14. You must update the record at the following intervals.
- Every 6 months for studies that are actively enrolling participants
- Annually for studies that are closed to enrollment and pending data results
- Within 30 days of a change in study status or any significant changes to the protocol record
  - for example; eligibility changes, study design, outcomes, etc...
- If Results Reporting is required per **FDAAA** regulation, results must be submitted no later than 12 months after the completion date.