Updating an account:

Instructions for updating studies:

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

3. Under Protocol records select Modify

4. Next screen sort as you would like and select

5. The next screen will indicate trials, select Edit button to the left of the trial you need to edit/update or release
6. Complete the record by selecting Edit next to each section that needs updating, if nothing has changed the minimal requirement is to update the **Record Verification Date** to the current month and year.

7. 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.

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

9. 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.

10. 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**.
    If a protocol returns with QA review comments, address comments and repeat release process.

11. If Personnel (Owner of Trial or Principle Investigator) change, inform your clinicaltrials.gov OSUMC Administrator’s (Vanessa Hill or Meliha Rahmani) of the change and please provide replacement contact.