EINSTEIN
Albert Einstein College of Medicine

ClinicalTrials.gov
Instructions for Updating a Study Record

1   Background

Studies listed as recruiting on the ClinicalTrials.gov website need to be updated at least every six months, or more often if there are ANY changes to the information presented in the ClinicalTrials.gov study template, including changes in recruitment status, contact persons, etc. Updates can be made at any time, as needed.

Updates are made in the Protocol Registration System (PRS) by the person who does the data entry on the study record. This person is called the "owner" of the study record.

2   To update the study record:

1. The owner needs to update the study record by going to https://register.clinicaltrials.gov/ and logging in using the organization name (MontefioreMC or Albert_Einstein), their individual Username and Password.

2. Locate the study and click on "Open" to view the record in more detail. Navigate to the section(s) you wish to update, open them, and edit the information.

3. Ensure that all other information associated with the registration is current and accurate.

4. Make sure to update the "Verification Date" in the Protocol Section, Study Status to reflect the current month and year that you completed your edit and re-review. The "Verification Date" is the field which generates automatic reminders within the PRS system, and cannot be left blank.

5. When done updating the record, please remember to hit "Completed" at the top of the template.

6. "Completed" at the top of the template means that you are done with the study record. Clicking on "Completed" is the only way the Einstein administrator knows to review and re-release your study record to ClinicalTrials.gov.

7. The Einstein administrator does not need any separate notification that your study is ready for release. The administrator will receive an automatic notification from the PRS system.

8. The Einstein administrator will release the study record to the ClinicalTrials.gov (PRS) team.

9. Publication of the update takes 2-5 business days because the PRS team does their own quality assurance check.