

ClinicalTrials.gov COVID 19 Information for Human Subjects Research Studies

1. Two activities are happening on ClinicalTrials.gov as a result of the COVID-19 pandemic:

- Registration of new clinical studies of COVID-19 disease.
 - Applicable Clinical Trials (by law) and clinical trials that receive direct NIH funding (NIH policy); registration is due within 21 days of first participant enrolled.
 - Registration should be *prior to the first participant being enrolled* to satisfy journal publication requirements.
- Updates to existing ClinicalTrials.gov records of studies that have been impacted by the situational response to the COVID-19 pandemic, including delays or pauses, and changes to the design or conduct of the study.
 - In general, ClinicalTrials.gov study records should be updated within 30 days of such changes.

2. If you are a Responsible Party or Member of a Research Team:

- You are still responsible (by law) for addressing any Errors, Problems, and PRS Comments associated with your records. Approve and Release updated information to ClinicalTrials.gov.
- We understand that you may be experiencing challenges conducting your research due to the Covid-19 pandemic and your research study might be delayed or may have needed to Pause as a result. If any of your Records are Experiencing **Delay or Pause Due to the COVID-19 Pandemic** you must temporarily suspend your study on clinicaltrials.gov.

To do this login to your account and:

- Change the Overall status of your trial from **Recruiting** or **Enrolling by Invitation** to **Suspended**.
- Reason for Suspension should be listed as: *Temporarily paused due to COVID-19 and expected to resume. This is not a suspension of IRB approval.*
- In addition, it is likely that the "anticipated" *Primary Completion Date* and the *Study Completion Date* will have to be moved forward. Please reassess these dates and any other areas of the record (i.e., anticipated enrollment number) that may be affected due to the pause. All milestone dates can be changed again later as needed.
- Address any additional Errors, Problems, and/or Comments associated with this record.

Note: Once the research restrictions are lifted, the Overall Status will need to be edited to the category that best reflects study enrollment activity. This is required within 30 days of when research resumes.

If you have any questions or need assistance making any of the required edits please contact clinicaltrials.gov@einsteinmed.edu. You can also refer to our [Clinicaltrials.gov FAQ sheet](#) for additional information.