Responses to Top Questions from Responsible Parties Related to Coronavirus (COVID-19)

NOTE: COVID-19 is an emerging, rapidly evolving situation. These responses will be updated as needed.

NIH recognizes that the COVID-19 public health emergency may impact ongoing research and the availability of organizations and staff for research-related activities, including submission of clinical trial information to ClinicalTrials.gov. These responses aim to address situations that Responsible Parties may face with managing clinical trial information in the ClinicalTrials.gov Protocol Registration and Results System (PRS).

Responsible Parties have asked about updating and correcting clinical trial information during this evolving situation. We reinforce the importance of making accurate and up-to-date clinical trial information available to the public on ClinicalTrials.gov, particularly for COVID-19 related research. However, due to the potential exceptional impact of this public health emergency on research-related staff availability, NIH acknowledges that delayed updates and corrections may be unavoidable. We expect clinical trial information to be updated or corrected as soon as any organization or staff-related delays are resolved and recommend that sponsors and investigators retain documentation that would allow for determination of the appropriateness of the delay.

1) How do Responsible Parties update the overall recruitment status of their study records and/or recruitment status of individual sites that close temporarily due to COVID-19?

Responsible Parties should update the Overall Recruitment Status or Individual Site Status in their study records. For more information, see the FAQ, When must I update clinical trial registration information?

To help ensure that accurate up-to-date clinical trial information is available, it is important to make any necessary changes to recruitment status on the Study Status page of the Protocol Section in the PRS. Refer to the list of recruitment status options and their definitions to determine the best answer based on the specific situation for your study. When the Overall Recruitment Status is a status other than Recruiting, the Individual Site Status data element no longer needs to be updated because the Overall Recruitment Status applies to each individual site. Note: If you select Suspended, Terminated, or Withdrawn as Overall Recruitment Status, you must provide a brief explanation for the reason why this study was stopped as part of the Why Study Stopped data element.

You may also provide additional information about the study status in the Detailed Description data element. When doing so, please include the date on which you added the information.

2) How does the Sponsor update a study record when a principal investigator designated as the Responsible Party is not available?

If the Principal Investigator designated by the Sponsor as the Responsible Party for the study is not able to update the record, then the Sponsor can change the Responsible Party. Select Sponsor in the Responsible Party data element on the Edit Sponsor/Collaborators page of the Protocol section. The PRS Administrator for your organization can then approve and release the record to ClinicalTrials.gov.
3) How can Responsible Parties for studies related to COVID-19 make their study records easily searchable?

Please include the World Health Organization (WHO) official acronym, COVID-19, in the Brief Title of records for studies that relate to the virus that causes COVID-19, known as severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). This will allow for easier identification of studies related to COVID-19. If the study is not related to SARS-CoV-2, please do not mention COVID-19 in the Brief Title.