

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 Note: If you select Suspended, Terminated, or Withdrawn as Overall Recruitment Status, you must provide a brief explanation for the reason why this study was stopped as part of the [Why Study Stopped](#) data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.

4) What can Responsible Parties do if they are unable to address all Major Comments in a record by the Corrections Expected date in the PRS due to COVID-19 related organization or staff-related delays?

Corrections Expected dates in the PRS are established by the Final Rule at 42 CFR 11.64(b) (i.e., 25 calendar days after receiving Major Comments for results information; 15 calendar days for registration information). If Responsible Parties are unable to address all Major Comments in a record by the Corrections Expected date, they should retain documentation that would allow later determination that the delay was appropriate. One option is to add an explanation in the Record Log clarifying why the Corrections Expected deadline cannot be met. This will become part of the record's permanent history. Responsible Parties should address all Major Comments in their records as soon as organization or staff-related delays are resolved.

Note that until Major Comments are addressed, study records for applicable clinical trials with results information will remain posted on ClinicalTrials.gov with the brief, standard Major Comments and a general note that the QC review process has not concluded. This is consistent with 42 CFR 11.52, which requires clinical trial results information to be posted on ClinicalTrials.gov not later than 30 calendar days after the date of submission, regardless of whether the quality control (QC) review process has concluded.

5) What can Responsible Parties do if they are unable to meet their deadline for submission of clinical trial results information due to competing COVID-19 responsibilities?

Responsible Parties for applicable clinical trials may submit a request to extend the results information submission deadline if they have "good cause." This includes "[e]mergencies that would prevent timely submission of clinical trial results information, including situations in which one or more data collection sites were affected by natural disasters or other catastrophes outside the responsible party's or sponsor's control." (81 FR 65076)

To submit an extension request, use the Delay Results link on the Record Summary page in the PRS. Extension requests must be submitted prior to the date results information would otherwise be due in accordance with the results information submission deadlines. (42 CFR 11.44(e)(1)(i)) Responsible Parties are required to submit a description of the reasons that they believe constitute good cause to justify an extension and an estimated extended results information submission date with sufficient detail to allow for evaluation of both requested components. (42 CFR 11.44(e)(ii))