Suggested Updates to ClinicalTrials.gov Status Information Based on Study Situation:

Please ensure that you have reviewed UMOR's COVID-19: Research Operations at U-M.

For studies registered in ClinicalTrials.gov that are undergoing a long term pause, this decision tool has been prepared by UMMS Regulatory Affairs and the UM Office of Research Compliance Review (ORCR) in line with current understanding of Federal and University guidance as of 3/27/2020. Please be aware that COVID-related guidances may continue to evolve. Principal Investigators may follow the recommendation below regarding ClinicalTrials.gov updates or contact Regulatory Affairs or ORCR for further consultation at their discretion.

Notes:

1. If other information in a ClinicalTrials.gov record facing the public is changing substantively (e.g., method of drug administration), under Federal Regulations, the record should be amended within 30 days.
2. For the suggested updates below, interaction means any remote or in-person interaction or intervention, in line with UMOR's COVID-19: Research Operations at U-M.

Studies that have not begun to recruit participants listed as "Not yet recruiting":
Status change is not required.
If "Anticipated Start Date" is approaching or recently past, we suggest updating the field to September or beyond. The study can always start sooner. Once the study does open, update ClinicalTrials.gov record accordingly, within 30 days of opening to recruitment and include "actual" start date.

Studies that have not yet enrolled any participants but are listed in ClinicalTrials.gov as "Recruiting":
Is the research involving human subjects continuing in line with UMOR's COVID-19: Research Operations at U-M?

- **Yes:** No change is needed to the ClinicalTrials.gov record status.
- **No:** Is enrollment still anticipated to begin despite COVID-19 research pauses?
    - **Yes**: No change is needed to the ClinicalTrials.gov record *until enrollment actually begins.* Within 30 days of first enrollment, change "Study Start Date" to "actual" and enter the date (day, month, year) of first enrollment.
    - **No:** Change study status to "Suspended" with the following notation: "Enrollment is temporarily paused due to COVID-19 and is expected to reopen in the future. This is not a suspension of IRB approval."

Studies that have begun recruiting, have already enrolled at least one participant, and are listed with a study status as "Recruiting":
Will recruitment continue during COVID-19?

- **Yes**: No change is required; status in ClinicalTrials.gov remains "Recruiting".
- **No:** Will intervention/interaction or data collection continue?
    - **Yes**: Change ClinicalTrials.gov status to "Suspended" with the notation: "Enrollment is temporarily paused due to COVID-19; interactions/interventions with current participants continue. This is not a suspension of IRB approval."
    - **No:** Change ClinicalTrials.gov status to "Suspended" with notation: "Enrollment and interactions/interventions are temporarily paused due to COVID-19 and are expected to resume in the future. This is not a suspension of IRB approval."

Studies that are listed as "Enrolling by invitation":
Will recruitment continue during COVID-19?

- **Yes**: No change is required; status in ClinicalTrials.gov remains "Enrolling by invitation".
- **No:** will intervention/interaction or data collection continue?
    - **Yes**: Change ClinicalTrials.gov status to "Suspended" with the notation: "Enrollment is temporarily paused due to COVID-19; interactions/interventions with current participants continue. This is not a suspension of IRB approval."
    - **No:** Change ClinicalTrials.gov status to "Suspended" with notation: "Enrollment and interactions/interventions are temporarily paused due to COVID-19 and are expected to resume in the future. This is not a suspension of IRB approval."

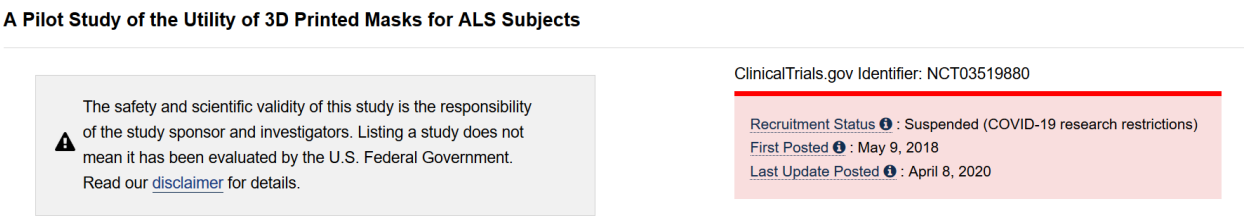
Studies that have already completed enrollment and are listed as "Active, not recruiting":
Will intervention, interaction, or data collection continue, as allowed under UMOR's COVID-19: Research Operations at U-M?

- **Yes**: No change is required; remain in "Active, not recruiting" status.
- **No:** Is the study pausing interventions/interactions but is expected to resume when COVID-19 restrictions are no longer in effect?
    - **Yes:** Change ClinicalTrials.gov status to "Suspended" with the notation: "Intervention/interactions are temporarily paused due to COVID-19 and are expected to resume. This is not a suspension of IRB approval."
    - **No: (the study is terminating early and no more data will be collected.)** Change ClinicalTrials.gov status to "Terminated", with an explanation about why the study terminated early, and enter date of last data collection for primary outcome measure as "Primary Completion Date", "Actual", and date of last data collection for all primary and secondary outcome measures as "Study Completion Date", "Actual" and the actual number of participants enrolled in the **Study Design Module.**
        - Is the study required to report results (ACT, NIH-funded, or required by Grantor)?
            - **Yes**: Contact Regulatory Affairs or ORCR to prepare a request to delay results submission or prepare for results reporting. Also, if NIH-funded and the trial began after 1/17/2017, prepare to submit informed consent document within 60 days of last data collection.
            - **No:** No further action is necessary.

Frequently Asked Questions

1) **Must I change my ClinicalTrials.gov status? If so, why?**
This depends on the trial's circumstances. Federal regulations require the study status to be updated within 30 days. Recent ClinicalTrials.gov guidance reinforces this obligation.

2) **Why should I use the term "Suspended" if some activities continue?**
The ClinicalTrials.gov definitions and terminology have some gaps. Because "Suspended" harmonizes better with the terminology in OnCore and CTRP reporting, the decision tool recommends "Suspended". Further, by using "Suspended" a free text box opens that allows for the explanation to sit right up front on the public facing ClinicalTrials.gov page, like this:



Using the language provided in the guidance document accomplishes two important things: it allows you to clarify whether enrollment or intervention or both are being paused, and it makes clear that this pause is not an IRB suspension (which has other regulatory implications.) The one drawback to a small number of trials is that if you use the term "Suspended", the contact information will be hidden from the public record. In this case, an alternative approach that the ClinicalTrials.gov guidance appears to endorse is to retain whichever status feels most accurate and add a note to the Detailed Description section. This note should include a) the "effective date"; b) a brief description of whether enrollment or interventions have been paused or changed; c) the final sentence required by the decision tool: "This is not an IRB suspension". For example: "4/3/20 Update: Recruitment is ongoing. Enrollment is temporarily paused due to COVID-19. Current participants remain active remotely. This is not a suspension of IRB approval."

3) **) I get a note warning me that the use of the language provided is more than the 80 character limit. Do I need to change the language?**
The IRB has reviewed and endorsed the language, so please try to use the exact language provided. Unlike Errors, notes do not prevent submission to ClinicalTrials.gov. The actual field length is 160 characters, and we designed the message for that purpose. The IRB requires that the final sentence be included to show that this is not an IRB suspension, which has regulatory significance.