



Worksheet: Protocol-Specific COVID-19 Risk Mitigation Planning

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The purpose of this worksheet is to provide investigators with general guidance and considerations when developing study-specific plans to modify research to ensure the ongoing safety of research subjects during the COVID-19 pandemic. Challenges to study conduct may arise, for example, from:

- Quarantines.
- Site closures.
- Travel limitations.
- Institutional policies or mandates that limit research activities.
- Interruptions to the supply chain for the investigational product.
- Other considerations if site personnel or trial subjects become infected with

These challenges may lead to difficulties in meeting protocol-specified procedures, including administering or using test articles or adhering to protocol-mandated visits and tests. The following worksheet contains various considerations when investigators are responsible for protocol-specific COVID-19 risk mitigation planning.

1. **General Exclusions:** If any of the following is true, development of a COVID-19 risk mitigation plan for research may not be needed.

- Research does not involve in-person interaction with research subjects.
- Research can be conducted as written while adhering to social distancing requirements and institutional COVID policies/requirements.
- Research is externally sponsored, and the sponsor has already developed a COVID-19 risk mitigation plan for the research.
- Research has been voluntarily placed on hold for recruitment and all research procedures (with the exception of necessary follow-up procedures required by the protocol to be done consistently with social distancing requirements and institutional policies/requirements).

2. **General Considerations for Creating a Study-Specific COVID-19 Risk Mitigation Plan.** The following are additional considerations for investigators when determining the various elements of their research that must be modified to ensure the ongoing safety of research subjects during the COVID-19 pandemic. The considerations below do not represent an exhaustive list and are intended to serve as a starting point to guide an ongoing discussion between investigators, study staff, sponsors and institutional review boards (IRBs) in their efforts to address the new risks to research subjects and others posed by the COVID-19 pandemic.

- Modifications to Recruitment and Enrollment Processes (Select any that are appropriate for the research.):
 - Temporarily discontinue study recruitment efforts and initiatives.
 - Temporarily discontinue enrollment of new research subjects.
 - Incorporate additional COVID-19 screening procedures for research subjects or study personnel that will be completed prior to recruitment and enrollment.
 - Other relevant actions should be taken. Describe: [Click or tap here to enter text.](#)
- Additional Modifications to Minimize Risk (Select any that are appropriate for the research.):
 - Withdraw some or all current research subjects from the research.
 - Modify study visit procedures so that visits can be completed via phone.
 - Modify study visit procedures so that visits can be completed virtually.
 - Modify study visit procedures so that visits can be completed at subjects' local lab, clinical or imaging center.



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	<ul style="list-style-type: none"> <input type="checkbox"/> Incorporate additional COVID-19 screening procedures for research subjects or study personnel that will be completed prior to in-person visits. <input type="checkbox"/> Incorporate other additional safety monitoring procedures. Describe: Click or tap here to enter text. <input type="checkbox"/> If planned on-site monitoring visits are no longer possible, consider optimizing use of central and remote monitoring programs to maintain oversight of clinical sites. <input type="checkbox"/> Modify timing and scope of specific study visits to account for essential versus nonessential study procedures. <input type="checkbox"/> Other relevant actions should be taken. Describe: Click or tap here to enter text.
<input type="checkbox"/>	<p>For FDA-Regulated Research: Modifications to Investigational Drug/Biologic/Device Access and Administration (Select any that are appropriate for the research.):</p> <ul style="list-style-type: none"> <input type="checkbox"/> For any investigational products that can typically be distributed for self-administration, modify the protocol to allow for alternative secure delivery methods (e.g., investigational product can be shipped to the subject's residence). <input type="checkbox"/> For any investigational products that are normally administered in a healthcare setting, consult FDA review divisions on plans for alternative administration (e.g., home nursing or alternative sites by trained but non-study personnel). <input type="checkbox"/> Other relevant actions should be taken. Describe: Click or tap here to enter text.
<p>3. Research Record and Study Documentation Considerations for COVID-19-Specific Study Modifications: The following are additional considerations for investigators when maintaining research records that reflect study modifications made to ensure the ongoing safety of research subjects during the COVID-19 pandemic.</p>	
<input type="checkbox"/>	<p>For protocol-wide study restrictions or modifications necessitated by COVID-19, documentation related to any of the following elements are included in the research record where applicable and appropriate to the research:</p> <ul style="list-style-type: none"> <input type="checkbox"/> Changes in study conduct <input type="checkbox"/> Duration of those changes <input type="checkbox"/> Which trial participants were impacted <input type="checkbox"/> How those trial participants were impacted <input type="checkbox"/> Other relevant actions that were taken. Describe: Click or tap here to enter text.
<input type="checkbox"/>	<p>For FDA-regulated research where there are individual instances when efficacy endpoints are not collected, the research record includes documentation related to the reasons for failing to obtain the efficacy assessment (e.g., identifying the specific limitation imposed by COVID-19 leading to the inability to perform the protocol-specified assessment).</p> <ul style="list-style-type: none"> <input type="checkbox"/> Specific information in case report forms explains the basis of any missing data, including the relationship to COVID-19 for missing protocol-specified information.
<input type="checkbox"/>	<p>For FDA-regulated research where changes in the protocol include any of the following, the research record includes documentation that changes were made in consultation with the applicable FDA review division where feasible and appropriate:</p> <ul style="list-style-type: none"> <input type="checkbox"/> Amendments to data management and/or statistical analysis plans <input type="checkbox"/> Alternative administration of investigational products that are normally administered in a healthcare setting (e.g., home nursing or alternative sites by trained but non-study personnel) <input type="checkbox"/> Protocol modifications for the collection of efficacy endpoints, such as use of virtual assessments, delays in assessments and alternative collection of research-specific specimens



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4. Communication Plan to Subjects: The following are additional considerations for investigators when maintaining research records that reflect study modifications made to ensure the ongoing safety of research subjects during the COVID-19 pandemic.

- A research subject communication plan describing the study-specific modifications being made to ensure the ongoing safety of research subjects during the COVID-19 pandemic has been developed for implementation with all current (and where applicable, prospective) research subjects. This plan includes:
 - What information will be communicated to current (and where applicable, prospective) research subjects.
 - Who will communicate the information
 - When the information will be communicated.
 - How the information will be communicated.

5. IRB Notification and Approval (Where Applicable): One of the following must be true.

- If immediate modification of the research is necessary to eliminate an apparent immediate hazard to a subject, take action and notify the IRB as a reportable event (RNI).
- For all other study modifications made to ensure the ongoing safety of research subjects during the COVID-19 pandemic, a study amendment is submitted to the IRB using "Form: Modification Due to COVID-19."