|  |  |  |
| --- | --- | --- |
| Protocol modifications may be required and there may be unavoidable protocol deviations due to COVID-19 illness and/or COVID-19 control measures. If changes to the research were implemented prior to IRB approval to eliminate immediate hazard to participants, please submit a New Information Report. This form is to be used for submissions of specific protocol modifications made to accommodate for COVID-19 issues. Refer to *HRP-092 – SOP: Study-Specific COVID-19 Risk Mitigation Planning* to determine if a modification needs to be submitted to the IRB for review.  Utilize the standard modification process when submitting this form – use the “Create Modification/CR” button on the study workspace, and select a modification to “other parts of the study” in the SmartForm. Upload this form in the “Other Attachments” section of the “Local Site Documents” page of the study SmartForm.[[1]](#footnote-1) | | |
| **Use to request a temporary change to previously approved activity due to the COVID-19 pandemic** | | |
| **IRB Number:** | |  |
| **Protocol Name:** | |  |
| **Investigator:** | |  |
| **Primary Contact:** | |  |
| **Protocol Status and Proposed Changes** | | |
| Describe the proposed changes to the research: | | |
| *Check all that are true* | | |
|  | There are subjects currently enrolled. Number of subjects currently enrolled: | |
|  | The study is currently open to enrollment | |
|  | Current subjects will continue use of investigational product via an alternative procedure. *(All below must be checked)*  Sponsor approves continued administration of the investigational product via alternative procedure  The study team can continue to conduct appropriate safety monitoring  Changes to patient monitoring include[[2]](#endnote-1) **(If none, indicate “n/a”)**: | |
|  | Subjects will receive notification of the changes to the conduct of the research **(required if subjects are enrolled in the study)**. ***(All below must be checked)***  Subjects will be asked to confirm their willingness to continue participation in the research  The plan for notifying subjects of the changes to the research is as follows: | |
|  | ***(Required)*** Additional protections to minimize risks to subjects during the course of contingency measures include: | |
|  | The data management and/or statistical analysis plan needs to be amended as a result of the contingency plan  The sponsor has consulted the FDA review division regarding the changes | |
| Provide the following documents as needed to support the COVID-19 contingency plan, if not already reviewed and approved by the IRB:   * Written materials to be provided to or meant to be seen or heard by subjects   + Evaluation instruments and surveys   + Consent addendum   + A script of information to be provided orally to subjects   + Recruitment materials and scripts   + Other communications developed specifically for your study’s COVID-19 risk mitigation plan (this excludes general institution-wide communications)   + Foreign language versions of the above * Complete sponsor contingency plan | | |

1. This document satisfies AAHRPP elements I.1.D, III.2.D [↑](#footnote-ref-1)
2. The implementation of alternative processes should be consistent with the protocol to the extent possible, and sponsors and clinical investigators should document the reason for any contingency measures implemented. Sponsors and clinical investigators should document how restrictions related to COVID-19 led to the changes in study conduct and duration of those changes and indicate which trial participants were impacted and how those trial participants were impacted. [↑](#endnote-ref-1)