|  |
| --- |
| FDA recognizes that protocol modifications may be required, and that 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 an RNI.  |
| **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***Check all that are true*  |
| Describe the proposed changes to the research:      |
| [ ]  | There are subjects currently enrolled. Number of subjects currently enrolled:       |
| [ ]  | The study remains 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[[1]](#footnote-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:* Written materials to be provided to or meant to be seen or heard by subjects
	+ Evaluation instruments and surveys1
	+ Consent addendum
	+ A script of information to be provided orally to subjects
	+ Recruitment materials and scripts
	+ Foreign language versions of the above
* Complete sponsor contingency plan
 |

1. 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. [↑](#footnote-ref-1)