**Study name:**       **Study PI:**

**Study ID #:**

**Protocol *Minor* Deviation Log for COVID-19 Disruption – No effect on subject safety or well-being**

This log tracks minor protocol deviations as the result of the pause in research in response to COVID-19. This form should be attached to the IRB submission at the time of continuing review or status check-in and to the sponsor (as applicable). Major deviations (increased risk to subjects) should be submitted on a Reportable Events and New Information form within 7 days.

* Visit missed – no contact with subject during protocol-required window
* Visit altered – deviation from protocol (remote contact instead of in-person, incomplete procedures, etc.)
* Comments – include how reported to sponsor, if applicable

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Subject ID #** | **Visit date** | **Deviation** | **Comments** | **Initials** |
|  |  | [ ]  Visit missed [ ]  Visit altered [ ]  Other (see comments) |  |  |
|  |  | [ ]  Visit missed [ ]  Visit altered [ ]  Other (see comments) |  |  |
|  |  | [ ]  Visit missed [ ]  Visit altered [ ]  Other (see comments) |  |  |
|  |  | [ ]  Visit missed [ ]  Visit altered [ ]  Other (see comments) |  |  |
|  |  | [ ]  Visit missed [ ]  Visit altered [ ]  Other (see comments) |  |  |
|  |  | [ ]  Visit missed [ ]  Visit altered [ ]  Other (see comments) |  |  |
|  |  | [ ]  Visit missed [ ]  Visit altered [ ]  Other (see comments) |  |  |
|  |  | [ ]  Visit missed [ ]  Visit altered [ ]  Other (see comments) |  |  |
|  |  | [ ]  Visit missed [ ]  Visit altered [ ]  Other (see comments) |  |  |
|  |  | [ ]  Visit missed [ ]  Visit altered [ ]  Other (see comments) |  |  |
|  |  | [ ]  Visit missed [ ]  Visit altered [ ]  Other (see comments) |  |  |
|  |  | [ ]  Visit missed [ ]  Visit altered [ ]  Other (see comments) |  |  |
|  |  | [ ]  Visit missed [ ]  Visit altered [ ]  Other (see comments) |  |  |
|  |  | [ ]  Visit missed [ ]  Visit altered [ ]  Other (see comments) |  |  |
|  |  | [ ]  Visit missed [ ]  Visit altered [ ]  Other (see comments) |  |  |
|  |  | [ ]  Visit missed [ ]  Visit altered [ ]  Other (see comments) |  |  |