**Study:**

**HRPO #:**

**PI:**

**Date:**

**Note:** Due to the COVID-19 pandemic, Washington University in St. Louis put restrictions in place regarding research activities starting March 23, 2020 until [date restriction is lifted]. These restrictions allowed for only essential personnel to complete essential research activities and visits. All other research activities were completed remotely.

**[For Sponsored Studies…]**

On [date], the sponsor was contacted about these restrictions.

**[If Protocol Changes Occurred…]**

The [sponsor/PI] determined a protocol change was necessary. [describe change(s)]

A modification was submitted to the IRB for this change on [date] and approved on [date].

**[If Sending IP…]**

A modification was submitted to the IRB on [date] and approved on [date] to allow for shipment of investigational products to participants in this study.

**[If No Protocol Changes Occurred…]**

The [sponsor/PI] determined no protocol change was necessary during this time.

The following participants were impacted by these restrictions: [list participant IDs]. Protocol deviations were written for the following participants and filed in the subject files: [list participant IDs].

|  |  |
| --- | --- |
| **Signature:** | **Date:** |
| **Role:** Clinical Research Coordinator | |

|  |  |
| --- | --- |
| **Signature:** | **Date:** |
| **Role:** Principal Investigator | |