TriHealth

Modification to the Protocol or Informed Consent Submission Form

TriHealth Institutional Review Board

1. Protocol / Study Staff Information

Study/IRB #: _____ **PI Name:** _____

Protocol Number: _____ ☐ check if N/A

Protocol Version/Version Date: _____

Title: _____

Sponsor: _____

Current Lead Study Coordinator/Research Specialist: _____

Current Sub-I (list all): _____

Age Range: _____

2. Current Study Status

Enrollment: ☐ Open ☐ Closed ☐ On Hold ☐ Suspended ☐ Has not started yet

Subjects: ☐ Active ☐ Not Active ☐ Follow-up only ☐ Data Analysis Only
☐ No subjects enrolled yet ☐ Chart Review ☐ Database Search ☐ Survey

Is enrollment closed to accrual? ☐ Yes ☐ No **If yes, date closed** _____

3. Approved Site(s)

☐ Good Samaritan Hospital ☐ Bethesda North Hospital

☐ TriHealth Physician Practice (please specify): _____

☐ Other (specify): _____

Site Address: _____

4. Contact Information for this submission:

Name:

Phone:

Email:

5. ☐ **Modification to the Protocol** ☐ **Check here if N/A**

Provide Revised Protocol Version #: **Revised Protocol Date:**

Does the modification to the protocol require changes to the Informed Consent? ☐ **Yes** ☐ **No**

Which of the following subjects do you intend to sign the revised consent? (check all that apply)

☐ **New Enrollees** ☐ **Current Subjects using device/taking study drug**

☐ **Current Subjects who are not using the device/not taking study drug (in follow-up) – No intervention**

☐ **Discontinued/Terminated/Completed subjects – no longer in the study**

☐ **Other (please specify):**

Does this modification to the protocol change the compensation: ☐ **Yes** ☐ **No** ☐ **check if N/A**

If yes, describe the revised payment schedule:

Does this modification to the protocol involve a sub-study? ☐ **Yes** ☐ **No**

If yes, (check all that apply)

☐ **Optional** ☐ **Mandatory** ☐ **Identifiable** ☐ **De-identified** ☐ **Single Coded**

Provide a detailed Summary of Changes to the protocol and reasons for the change:

6. ☐ **Modification to the Informed Consent** ☐ **Check here if N/A**

Which of the following subjects do you intend to sign the revised consent? (check all that apply)

☐ **New Enrollees** ☐ **Current Subjects using device/taking study drug**
☐ **Current Subjects who are not using the device/not taking study drug (in follow-up) – No intervention**
☐ **Discontinued/Terminated/Completed subjects – no longer in the study**
☐ **Other (please specify):**

Provide a detailed Summary of Changes to the informed consent and reasons for the change:

7. ☐ **Modification to Other (i.e. recruitment material, study related materials, data collection forms, Patient brochures)** ☐ **Check here if N/A**

Does the modification to other require changes to the Informed Consent? ☐ **Yes** ☐ **No**

Which of the following subjects do you intend to sign the revised consent? (check all that apply)

☐ **New Enrollees** ☐ **Current Subjects using device/taking study drug**
☐ **Current Subjects who are not using the device/not taking study drug (in follow-up) – No intervention**
☐ **Discontinued/Terminated/Completed subjects – no longer in the study**
☐ **Other (please specify):**

Provide a detailed Summary of Changes to other and reasons for the change:

8. Modification Requested by:

I attest that I will not implement the changes stated above until the TriHealth IRB has granted approval of this request. I confirm I will abide by the requirements of TriHealth and the IRB, as per the Researcher's Responsibilities, Federal and State Regulations, and the agreement with the sponsor in the conduct of the protocol.

Signature of Principal Investigator	**Date**

Submit modification forms and supporting documents to irb_hrpp@trihealth.com

Please note if your submission is incomplete, processing will be delayed.