TriHealth

*Safety Submission Form*

**TriHealth Institutional Review Board**

1. **Protocol Information:**

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

**Protocol Number:** ☐ **check if N/A**

**Protocol Version/Date:**

**Title:**

**Sponsor:**

**Age Range:**

2. **Contact Information for this submission:**

**Name:**

**Phone:**

**Email:**

3. **Submission Type:**

**Please provide Version#/Version Date/Rev # if applicable for each item:**

**Revised Investigator Brochure:** ☐ **Yes** ☐ **No**

**Package Insert:** ☐ **Yes** ☐ **No**

**Annual Device Status:** ☐ **Yes** ☐ **No**

**DSMB/DMC:** ☐ **Yes** ☐ **No**

**Other:** ☐ **Yes** ☐ **No (please specify):**

**4. Modifications required?**

**Does this safety submission result in the need for modification of the protocol?**

☐ **Yes** ☐ **No**

**Does this safety submission result in the need for modification of 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):** _____

**5. Current Study Status: (check all that apply)**

**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**

**6. Safety Information submitted by:**

**Signature of Principal Investigator:** _____

**Date:** _____

**Submit safety forms and supporting documents to irb_hrpp@trihealth.com**
**Please note if your submission is incomplete, processing will be delayed.**