# IND-IDE Safety Submission Form

## TriHealth Institutional Review Board

1. **Protocol Information**

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

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

**Protocol Version/Date:** _____

**Title:**

_____

**Sponsor:** _____

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

**Name:** _____

**Phone:** _____

**Email:** _____

3. **Current Study Status**

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

**Subjects:** ☐ **Active** ☐ **Not Active** ☐ **Follow-up only** ☐ **Data Analysis On**

☐ **No subjects enrolled yet** ☐ **Chart Review** ☐ **Database Search** ☐ **Survey**

**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**

**Does this safety submission result in the need for modification of the Investigator Brochure, Package Insert(s) or Device Manual?**

☐ **Yes** ☐ **No**

**Attach the Serious Adverse Event Report (i.e., Medwatch) received from the sponsor requiring submission to the IRB and list report numbers below:**

**5. Safety information submitted by:**

**Signature of Principal Investigator**

**Date**

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