Unanticipated Problem Submission Form

TriHealth Institutional Review Board

MUST BE SUBMITTED WITHIN 5 BUSINESS DAYS OF OCCURRENCE OR

WITHIN 24 HOURS IN THE EVENT OF DEATH

THE EVENT MUST BE UNANTICIPATED/UNEXPECTED, RELATED AND SERIOUS

1. Protocol Information

Study/IRB Number: **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. Current Study Status: (check all that apply)

Enrollment: ☐ **Open** ☐ **Closed** ☐ **On Hold** ☐ **Suspended**

Subjects: ☐ **Active** ☐ **Not Active** ☐ **Follow-up Only** ☐ **Data Analysis Only**

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

4. Subject Information

Subject ID and Subject Initials:

Subject Status:

☐ **Active** ☐ **In Follow-up** ☐ **Withdrawn, indicate reason:**

Date of Unanticipated Problem (event):

Has the sponsor be notified of the Unanticipated Problem?

☐ **Yes** ☐ **No** ☐ **N/A** **If No, date sponsor will be notified:**

5. Type of Event (check all that apply):

☐ **Breach of confidentiality**

☐ **Failure to obtain approval from Board for change in Research Activities**

☐ **Misconduct of study staff that affects the integrity of the study**

☐ **Subject Complaint**

☐ **Adverse Audit Results from regulatory agency or sponsor**

☐ **Failure to maintain proper medical licensure**

☐ **Legal Risk to subjects**

☐ **Adverse events of greater frequency or severity than originally anticipated**

☐ **Other:**

6. Unanticipated Problem Information

Provide a detailed description of the unanticipated problem (i.e., clinical summary & outcome of the event), including how the unanticipated problem places the subjects or others at increased risk and how it has been resolved:

Does this unanticipated problem result in the need for modification of the protocol?

☐ **Yes** ☐ **No**

Does this unanticipated problem result in the need for modification of the Informed Consent?

☐ **Yes** ☐ **No**

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

☐ **Yes** ☐ **No**

6. Unanticipated Problem Information continued

Describe corrective measures that have been put in place to avoid re-occurrence: ☐ N/A

7. Unanticipated Problem submitted by:

Signature of Principal Investigator **Date**

If you have questions regarding what constitutes an Unanticipated Problem refer to the **FDA Guidance for Clinical Investigators, Sponsors, and IRBs Adverse Event Reporting to IRBs — Improving Human Subject Protection.**

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

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