TriHealth

Continuing Review Form

TriHealth Institutional Review Board

1. Submission Information

☐ Continuing Review

☐ Interim Reporting - Time Period covered in Report:

2. 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:

3. Current Study Status

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

Explain reason for no or minimal research activity during the review period

Subjects: ☐ No subjects enrolled yet ☐ Active ☐ Follow-up Only
☐ Data Analysis Only ☐ Chart Review ☐ Database Search ☐ Survey

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

4. Approved Sites

☐ Good Samaritan Hospital ☐ Bethesda North Hospital

☐ TriHealth Heart Institutes

☐ TriHealth Physician Practice (please specify):

☐ Other (specify):

5. Contact Information for this submission

Name:

Phone:

Email:

6. Modifications

Have you modified the study since the last IRB review? ☐ Yes ☐ No

If no, skip to #7 - Activity Information

Protocol Change: ☐ Yes ☐ No

Informed Consent Change: ☐ Yes ☐ No

Change of PI: ☐ Yes ☐ No

Other (specify): ☐ Yes ☐ No

Have all the modifications been approved by this IRB? ☐ Yes ☐ No

If not, please submit as soon as possible.

7. Activity Information **If HDE/HUD study, check box and skip to Section #9** ☐

A. Provide the APPROVED sample size for the overall study (as stated in protocol)	**(A)**
B. Provide the APPROVED sample size for the TriHealth sites	**(B)**
C. **1. *Clinical Trials/Prospective Academic Trials:* Just in the time period covered in this year's report, how many subjects signed a TRIHEALTH consent?** **OR** **2. *Retrospective Academic Trials:* How many medical charts reviewed/ surveys sent since your last report?** • **Provide number of charts that meet eligibility criteria**	**(C1)** **OR** **(C2)** **(C2a)**
D. **1. *Clinical Trials/Prospective Academic Trials:* Total number of subjects that signed a TRIHEALTH consent since your study was approved?** **2. *Retrospective Academic Trials:* Total charts meeting eligibility criteria/ surveys sent to date?**	**(D1)** **OR** **(D2)**

8. Subject Summary **If Chart Review study, check box and skip to Section #12** ☐

E. How many subjects have <u>completed</u> the study:	**(E)**
F. How many subjects have <u>screen failed</u>*:	**(F)**
G. How many subjects are <u>actively receiving treatment</u>:	**(G)**
H. How many subjects are in <u>follow-up only</u>:	**(H)**
I. How many subjects have dropped/withdrawn (subject withdrew, physician withdrew subject due to unanticipated problems, death or other reasons): **If subject(s) have been dropped/withdrawn please provide details in Section 12**	**(I)**
J. (The total of E + F + G + H + I must = D1 in the Activity Section above)	**(J)**
K. Total number of subjects enrolled in a multi-center study, if applicable	**(K)**
L. Duration of subject participation, if applicable	**(L)**
M. Number of visits during study, if applicable	**(M)**

***Screen Failed – participant fails to meet the inclusion criteria after providing consent and is withdrawn from the study.**

9. Is this a HUD/HDE? ☐ **Yes** ☐ **No - If Yes, please complete the questions below:**

As this is a HUD, some additional information is needed for Continuing Review:

1. **Please provide the number of deployments that have occurred since the last report, as well as providing the total number of deployments that have occurred since the initial approval of this HUD with TriHealth IRB.**

   Total # of deployments that have occurred since the last continuing review
   Total # of deployments that have occurred since the initial approval

2. **Please confirm if any of these deployments were Off-Label?** ☐ **Yes** ☐ **No**

   - **Was documentation of any Off-Label deployments submitted to the IRB?** ☐ **Yes** ☐ **No**
   - **If No, please submit documentation of any Off-label deployments.**

3. **Is an Information Sheet/Patient Booklet given to subjects?** ☐ **Yes** ☐ **No**

4. **Have any Manufacturer Device Reports (MDRs) been submitted to the FDA as required by (21 CFR 814.126(a))?** ☐ **Yes** ☐ **No**

   - **If Yes, was/were the MDR(s) reported to the IRB.**

5. **Have there been any labeling changes in the device since last renewal?** ☐ **Yes** ☐ **No**

   - **If Yes, was labeling change reported to TriHealth?**
   - **If No, please submit the labeling change.**

6. **Have any physicians been added to the list of those deploying the device?** ☐ **Yes** ☐ **No**

   - **If Yes, was addition of physician(s) report to the IRB?**
   - **If No, please provide CV, license, evidence of training (as applicable), and signed attestation letter.**

10. Demographic Information (for those subjects who signed an informed consent)

If not collecting demographic information please check the box ☐

	American Indian or Alaskan	Asian	Black, not of Hispanic-American Origin	Hispanic-American	White, not of Hispanic-American Origin	Hawaiian or Pacific Islander	Other or Unknown	Total
Female								
Male								
Total								*

(*Total must equal line D1 in the Activity section)

11. Injury, Complaints, Significant Findings in the time period covered in this report ☐ Yes ☐ No*

*If no, skip to #12 - Unanticipated Problems/Withdrawal from the Study

Have any subjects sought compensation for injury: ☐ Yes ☐ No

Have any subjects made complaints regarding the conduct of the study:

☐ Yes ☐ No If yes, how many?

Have there been any significant findings that may affect a subject's willingness to stay in the study:

☐ Yes ☐ No

Has anything occurred in this study that would change the risk/benefit analysis of the study:

☐ Yes ☐ No

Have you consented subjects from any of the following groups: ☐ Yes ☐ No ☐ N/A

If yes, check all that apply:

☐ Anyone who cannot read ☐ Employees or family members of employees

☐ non-English speaking subjects ☐ Consented via LAR

12. Unanticipated Problems/Withdrawal from the Study

Did any unanticipated problems involving risk to subjects or others occur during the reporting period?

☐ Yes ☐ No

If yes, please provide a description of the event(s):

Were these reported to the IRB, to the sponsor, to the FDA or to anyone else? ☐ Yes ☐ No

If yes, to whom:

Did you remove <u>ANY</u> TRIHEALTH subject from the study due to unanticipated problems, noncompliance or other reasons (since the beginning of the study)? ☐ Yes ☐ No

If yes, please provide a description of the medical problem or other circumstances for each subject who was terminated involuntarily.

12. Unanticipated Problems/Withdrawal from the Study (continued)

Did ANY TRIHEALTH subject voluntarily withdraw from the study for medical or non-medical reasons (since the beginning of the study)?

☐ **Yes** ☐ **No**

If yes, please provide a description of any known reasons for such subject who withdrew.

Have there been any subject deaths since last IRB Review?

☐ **Yes - Number of subjects who have died** ☐ **No**

13. Compliance

In the time since your last continuing review

Have there been any items of non-compliance with the protocol or regulations:

☐ **Yes *** ☐ **No**

If yes, have you reported them to TriHealth IRB: ☐ **Yes** ☐ **No**

If No, List Reason Why:

*** Complete the Protocol Deviation Log Form ONLY when you have checked YES to the question above.**

14. Regulatory Issues

Since your last continuing review:

Has any investigator involved with this study:

Had sponsor, CRO, IRB suspended, terminated, imposed restrictions or refused to review a protocol? ☐ **Yes** ☐ **No**

Had the FDA, OHRP terminated the study? ☐ **Yes** ☐ **No**

14. Regulatory Issues (continued)

Had a state medical board taken disciplinary action against his/her license?

☐ **Yes** ☐ **No**

Are there state medical board complaints and/or charges pending against any investigator: ☐ **Yes** ☐ **No**

Since your last continuing review:

Has this site and/or any investigator involved with this study been audited by the FDA or OHRP:

☐ **Yes** ☐ **No**

15. Conflict of Interest

During the past 12 months, has any investigator or Lead Coordinator/Specialist involved in this study and/or their immediate family or household members had any changes in their previously reported financial interests?

☐ **Yes** ☐ **No**

If YES, a new Conflict of Interest in Clinical Research Compliance Questionnaire must be completed for each individual.

16. CERTIFICATIONS AND APPROVALS

I attest that this report is accurate, complete and reflects the status of the study/protocol as of this date. 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 continuing reviews or final reports to irb_hrpp@trihelath.com

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