Final Study Closure Submission Form

1. Study Information

Study Title:	
Protocol Version/Date:	
Hatton / IRB #:	
Sponsor*:	

***If your study is sponsored by a company/group/institution outside of TriHealth, the TriHealth IRB will NOT close your study at TriHealth without written approval (for example, a memo, site closeout letter, or e-mail) from the study sponsor. Written approval from the study sponsor for study closure MUST be included in your Final Study Closure Submission to the IRB.**

2. TriHealth Principal Investigator & Research Team Information

Principal Investigator Name:	
TriHealth E-mail:	

Lead Coordinator/ Specialist Name:	
TriHealth E-mail:	

Name of Regulatory Support Staff:	
TriHealth E-mail:	
Telephone Number:	

3. Please indicate the TriHealth location(s) where the research was conducted:

☐	Good Samaritan Hospital (375 Dixmyth Ave. Cincinnati, OH 45220)
☐	Bethesda North Hospital (10500 Montgomery Rd., Cincinnati, OH 45242)
☐	TriHealth Physician Practices (identify below)
☐	Other TriHealth locations:

4. Study Results

Yes	No	
☐	☐	**Study results are included in your Final Study Closure Submission to the IRB.**

If you answered "No" to the above item, please explain why study results are not included in your IRB submission.

5. Please Confirm the Circumstance for Study Closure

Yes ☐	No ☐	The study team at TriHealth site locations will **NO LONGER obtain, use, analyze, and/or generate** identifiable private information and/or identifiable biospecimens about/from any living person for study purposes.
Yes ☐	No ☐	All research activities at TriHealth site locations are complete (including data analysis and reporting).
Yes ☐	No ☐	Record-keeping and record retention at TriHealth will be maintained per applicable regulations and TriHealth Hatton Research Standard Operating Procedures.
If you answered "No" to any of the above items, please provide regulatory rationale for closing your study at TriHealth.		

6. Summary of Study Activity

Date Principal Investigator closed study at TriHealth:	
Date subject enrollment was completed at TriHealth:	
IRB approved subject sample size:	
Number of subjects who completed the study at TriHealth (or number of charts or records that were collected at TriHealth)	
Number of subjects who completed the study across sites (TriHealth sites and all other site locations outside of TriHealth):	
Number of screen-fail subjects at TriHealth:	
Number of dropped/withdrawn subjects at TriHealth (subject withdrew, physician withdrew subject, death)	

If not previously reported to the IRB, explain the circumstances for each subject who was terminated from the study involuntarily at TriHealth **OR** indicate this is not applicable (NA) to your study:

7. Protocol Deviations and Non-Compliance

Yes ☐	No* ☐	Not Applicable (No Protocol Deviations at TriHealth) ☐	**All Protocol Deviation Logs/Reports compiled by the TriHealth study team have been reviewed by TriHealth IRB.**
Yes ☐	No* ☐	Not Applicable (No Non-Compliance at TriHealth) ☐	**Non-Compliance with the protocol requirements and/or regulations by the TriHealth study team has been reviewed by the TriHealth IRB.**

If you answered "No" to any of the above items, please include any TriHealth Protocol Deviation Reports and/or Non-Compliances Reports that have not yet been reviewed by the TriHealth IRB in your Final Study Closure Submission to the IRB.

8. Summary of Injury, Complaints, and/or Problems

Yes ☐	No ☐	Have any subjects sought compensation for injury?
Yes ☐	No ☐	Have any subjects made complaints about the study?
Yes ☐	No ☐	Did any unanticipated problems involving risk to subjects or others occur during the study?
Yes ☐	No ☐	Have there been any significant findings during the study that may have impacted a subject's willingness to stay in the study?
Yes ☐	No ☐	Has any investigator involved with the study had a sponsor, CRO, IRB, FDA, OHRP suspend, terminate, and/or impose restrictions on any research?
Yes ☐	No ☐	Has a state medical board taken disciplinary action against a license of any of the investigators involved with the study?
Yes ☐	No ☐	Has the TriHealth site or any of the investigators involved with the study been audited by the FDA or OHRP during their conduct of the study?

If you answered "Yes" to any of the above items, please explain OR indicate that the issue was previously reported to and reviewed by the IRB:

CERTIFICATION AND APPROVAL

I attest that the information on this form is accurate, complete, and reflects the status of the study as of this date. I confirm that I will abide by the requirements of TriHealth and TriHealth IRB, as per the TriHealth Principal Investigator Responsibility List, applicable regulations, and any agreement with the study sponsor.

Signature of Principal Investigator	Date

Please submit your Final Study Closure Submission Form and any supporting documents to **irb_hrpp@trihealth.com**. If you have questions about this form, please call **513-865-5248**.