The Christ Hospital Health Network Institutional Review Board	INVESTIGATIONAL DEVICE FORM

The Christ Hospital Institutional Review Board SOP 2.01 Guidelines for Protocol Submission

IRB #:	
PI Name:	
Study Title:	

Name of Device:	
Model:	
Manufacturer:	

Has this device been approved by the FDA?	☐ Yes	☐ No
If yes, Does the proposed research use the device for the purposes for which it has been approved?	☐ Yes	☐ No

Indicate device status (check as many as apply)

☐ Investigational Device Exemption (IDE) Number:_____

or

☐ FDA Exemption Letter

☐ Significant Risk Device

☐ Non-Significant Risk (NSR) Device

-Attach a letter from the sponsor discussing the reasons for the risk classification.

☐ Commercially available

☐ Other _____

Will device be billed to participants?	☐ Yes	☐ No
If **No,** who will pay for this device:		

Will a Data and Safety Monitoring Board (DSMB) review the data from this study?

☐ **Yes** (complete Items a-e)

☐ **No** (and the research involves greater than minimal risk, complete Item f)

a. Who will make up the DSMB:

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b. Will there be an Interim Analysis?:
c. At what points will the data be reviewed?:
d. Describe how the plan will work:
e. State any differences in the serious adverse event reporting between this particular protocol and 45 CFR 46 or 21 FR 312 (or enter "None"):
f. Describe the plan for monitoring the data to ensure the safety of participants (Describe what data will be monitored, how often it will monitored, who will monitor it, what data will be evaluated, and the decisions that will be made in response to the evaluation):

Report of handling, shipping and storage, release procedure and documentation of investigational devices *(Note: Must maintain records for a period no less than 2 years after FDA approval or longer, if required by the sponsor, in accordance with FDA regulations)*		
Does the investigator hold an IDE?	☐ Yes	☐ No
Will device handling, storage, and documentation be tracked without an independent monitor (e.g, CRO, other specified person)?	☐ Yes	☐ No
If No, name of monitor:		
List personnel who are trained and qualified to use the device:		
Describe the plan for handling, shipping and storage, control, and dispensing of the device so that only authorized investigators will use the device and they will use the device only in participants who have provided consent:		

_____ **Name (Printed or Typed)**	
_____ **Signature**	_____ **Date**