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CVRx Barostim™ Investigator-Initiated Research Initial Proposal

By completing this form, you are providing CVRx with basic information on your proposed study including preliminary budget and publication plan. This information will be shared with the CVRx Barostim™ Investigator-Initiated Research (BIIR) committee to determine if it can be supported. If CVRx conditionally approves funding for your proposal, you will be required to submit a complete protocol, a comprehensive study timeline, full study budget and a full publication/presentation plan.

Please complete as much of this form as possible, as incomplete forms may result in delays.

Please attach the following documents to this form when submitting:

- ☐ Current signed CV
- ☐ Current medical license
- ☐ Proposed budget
- ☐ Contact Information for the Investigator making this request:

  Phone number:

  Email:

If you have any questions about completing this document or the investigator-initiated research process, please contact us at BarostimIIR@cvrx.com.

Please submit this initial proposal form, the proposed budget and the above listed documents (CV and license) to the following e-mail address: BarostimIIR@cvrx.com. We will respond to your e-mail within 5 working days with estimated timeline for review.

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Study Name		
Title of proposed study:		
Site Information		
Investigator(s) participating in proposed study:		
Institution(s) where study will be conducted:		
IRB/EC name:		
Research coordinator contact information:	Name: Phone Number: Email:	
Experience		
Research experience:	Have you conducted clinical research before? Choose an item. Have you conducted Investigator Initiated Research before? Choose an item. Do you have documented GCP training? Choose an item.	
Quality control measures:	Does your site have clinical Standard Operating Procedures (SOPs)? Choose an item. Does your site have quality control processes in place (i.e. monitoring/audit)? Choose an item. Will the data be housed in 21 CFR Part 11 compliant database (21 CFR Part 11)? Choose an item. If no, please specify location:	
Design and Devices		
Research within approved labeling (Instructions for Use):	Choose an item.	
Core lab(s):	Choose an item. Name of lab:	
Study design:	Type of study: Choose an item. Design of study: Choose an item.	Number of sites: Choose an item. Identify arms or comparator:
Data Collection:	Collection type: Choose an item. Specify other type:	
Study population and/or disease focus:		

Total sample size (and number of subjects in each arm if >1 arm):		
Inclusion criteria:		
Exclusion criteria:		
Rational and Endpoints		
Study Synopsis:		
Rationale & background:		
Primary endpoint(s):		
Secondary endpoint(s):		
Data Collection and Follow-Up		
Basic data points to be collected:		
Will data be monitored:	Choose an item. By whom:	
Will economic data be collected?	Choose an item. Name economic data points:	
Preliminary data available:	Choose an item. (Please attach data to proposal)	
Study timeline	Study completed within:	Choose an item.
	Please provide estimated timeline from study start to manuscript submission:	
	Subject follow-up: Choose an item. Other (define):	

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Duration of subject follow-up	Please list how many visits will occur, and windows for the visits:
Funding and Publication	
Requested funding:	☐ Initial budget attached: Total $ amount: ☐ Requesting in-kind services (i.e. database use, assistance in protocol development, assistance with manuscripts, etc.)
Previous submissions of this proposal:	Funding Request: Choose an item. Please indicate other source(s):
Publication/ presentation plan:	☐ Podium Presentation – name of conference: ☐ Journal Article – name of journal:

By signing this form, I agree that:

☐ I am the sponsor and investigator for this proposed study, and

☐ I and/or my institution have the resources and ability to perform the sponsor responsibilities, and

☐ This is my original study idea, and

☐ I have not received help from a CVRx employee in developing this idea/proposal, and

☐ I will use all devices per the Instructions for Use when completing data collection for this proposal.

Investigator Signature: _____ Date: _____