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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? ☐ Yes ☐ No Have you conducted Investigator Initiated Research before? ☐ Yes ☐ No Do you have documented GCP training? ☐ Yes ☐ No
Quality control measures:	Does your site have clinical Standard Operating Procedures (SOPs)? ☐ Yes ☐ No Does your site have quality control processes in place (i.e. monitoring/audit)? ☐ Yes ☐ No Will the data be housed in 21 CFR Part 11 compliant database (21 CFR Part 11)? ☐ Yes ☐ No, if no, please specify location:
Design and Devices	
Research within approved labeling (CVRx HFrEF Labeling):	◯ Yes ◯ No
Core lab(s):	◯ Yes, name: ◯ No
Study design:	◯ Prospective ◯ Retrospective ◯ Single Center ◯ Multi-center ◯ Single Arm If yes: comparator: ◯ Multi Arm Identify arms:
Data Collection:	◯ Consecutive ◯ Random sampling ◯ Other (identify how collecting):
Study population and/or disease focus:	
Total sample size (and number of subjects in each arm if >1 arm):	
Inclusion criteria:	
Exclusion criteria:	

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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:	◯ Yes, by whom: ◯ No
Will economic data be collected?	◯ Yes, name data points: ◯ No
Preliminary data available:	◯ Yes (please attach data to proposal) ◯ No
Study timeline	<u>Study completed within:</u> ◯ Less than 3 months ◯ 3-6 months ◯ 6-12 months ◯ greater than 1 year
	Please provide estimated timeline from qualification to manuscript submission:
Duration of subject follow-up	<u>Subject follow-up</u> ☐ Acute ☐ 30 day ☐ Up to 6 months ☐ Up to 1 year ☐ Greater than 1 year ☐ Other (define):
	Please list how many visits will occur, and windows for the visits:

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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:	○ This is the 1st time you have requested funding for this proposal ○ You have requested funding for this proposal from another source (please indicate source):
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 System Reference Guide when completing data collection for this proposal.

Investigator Signature: _____ Date: _____