CVRx®

CVRx BAROSTIM™ Investigator-Initiated Research Overview

Thank you for your interest in CVRx and the BAROSTIM™ Investigator-Initiated Research (BIIR) program. CVRx is dedicated to supporting IIR to generally advance scientific knowledge through the support of IIR proposals from investigators and specifically to further generate evidence to support the improvement of patient care and outcomes using BAROSTIM THERAPY™. Each submission is evaluated by the BIIR committee for scientific merit, novelty, and alignment with CVRx's strategic focus.

Although CVRx may provide funding and limited technical and/or other support for approved BIIR proposals, CVRx is not the sponsor of these research / studies. The investigator and/or investigator's institution is the sponsor of the research or study, and is therefore responsible for the design, conduct, and outcome of the research, as well as understanding and complying with all regulatory requirements related to the research.

As you submit a proposal for BIIR funding and support, please be aware of the responsibilities, considerations and requirements outlined below.

The investigator, as the sponsor, is responsible for:

- Research / study design, writing the protocol
- Research / study conduct according good clinical practice (GCP) guidelines (https://www.fda.gov/science-research/science-and-research-special-topics/clinical-trials-and-human-subject-protection)
- Obtaining appropriate subject consent and rights to collect and use the data
- Ensure control and validity of the data generated
- Obtaining compliance with all applicable regulatory requirements
- Oversight of the research / study
- All other relevant roles and responsibilities of being a sponsor (e.g. IRB submissions, study registration, adverse event reporting, monitoring)

Obligations of the investigator, under the CVRx BIIR Program include:

- Disclosing experience, credentials and business affiliations
- Meeting research / study agreement obligations, including deadlines
- Providing progress reports and updates as determined by the agreement
- Providing draft publication materials upon completion of the study / research

Considerations for appropriate research proposals may include:

- Prospective studies, within the approved labeling, to assess effects of BAROSTIM NEO™ that are novel and consistent with CVRx strategic focus
- Use of existing data for additional analysis
- Retrospective studies

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Research / studies must include, if appropriate:

- Comprehensive study design consistent with appropriate use of BAROSTIM THERAPY within the indication for use
- Statistical analysis plan that documents sample size and planned analyses
- Reasonable and feasible follow-up timelines
- Appropriate site and investigator qualifications
- Ability for site and/or investigator to fulfill the regulatory and logistical requirements for conducting the research (e.g. support staff, equipment, time, database, monitoring)
- Approved fair market value budget that includes all study-related costs
- Clearly defined milestones with ongoing and timely reports on the progress of these research / study milestones. **NOTE: These milestones determine timing of research / study payments from CVRx.**

Required Information for initial request:

- An initial study proposal
- Preliminary budget
- Information about your research experience and available resources
- Investigator(s) CV(s) and medical license(s)

The CVRx BIIR committee will evaluate the proposed study solely on the information contained in the initial proposal and budget, so please fill these documents out as completely as possible and provide enough information to accurately describe the proposed research / study. If the proposal is conditionally approved by the committee, a full protocol, detailed budget and study timelines will need to be submitted before final approval can be made. Release of funding and/or products is subject to the execution of a contract between CVRx and the Investigator, and research / study approval by the applicable IRB or Ethics Committee.

For more information about the CVRx BAROSTIM Investigator-Initiated Research program, please contact us at BarostimIIR@cvrx.com.