 **Investigator Initiated Research**

**Project Proposal Form**

***The LivaNova Investigator Initiated Research program provides support for research that advances medical and scientific knowledge about LivaNova products. The following information will be used to assess the scientific merit of the proposed research and alignment with corporate research and development plans. Submissions will be reviewed by the LivaNova Investigator Initiated Research Review Board.***

***For additional information or to submit completed forms and supporting documentation, please contact*** ***livanova.iir.acs@livanova.com*** ***for requests related to the Advanced Circulatory Support portfolio,***  ***or*** ***livanova.iir.nm@livanova.com*** ***for requests related to the Neuromodulation portfolio.***

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| **Section 1. Supporting Documentation** |
| ***Please enclose the following supporting documentation:*** [ ]  Signed and dated Curriculum Vitae (CV) for Investigator and Sub-investigator(s) including evidence of Good Clinical Practice training *(required)*[ ]  Letter of support from institution *(required)*[ ]  Disclosures of any sponsor or regulatory letters or actions in the past 5 years concerning any study conduct deficiencies, or unsatisfactory Investigator or study-site conduct OR confirmation that there have been no sponsor or regulatory letters or actions in the past 5 years concerning any study conduct deficiencies, or unsatisfactory Investigator or study-site conduct. *(required)*[ ]  Copy of Final Study Protocol *(if available)*[ ]  Copy of Ethics Committee (EC) / Institutional Review Board (IRB) approval *(if available)* |
| **Section 2. Site Information** |
| **Primary Investigator**  | **Name:** |
| **Research Institution:** |
| **Mailing Address:** |
| **Email:** | **Phone:** |
| **Years of Clinical Trial Experience:** |
| **Sub-Investigator(s)** | **Name:** |
| **Research Institution:** |
| **Mailing Address:** |
| **Email:** | **Phone:** |
| **Years of Clinical Trial Experience:** |
| **Study Coordinator**  | **Name:** | **Phone:** |
| **Email:** |
| **Years of Clinical Trial Experience:** |
| **Legal Contact for Research Agreement** | **Name:** | **Phone:** |
| **Email:**  |
| **Contact for Budgets and Invoices** | **Name:** | **Phone:** |
| **Email:**  |
| **Section 3. Compliance and Capability of Investigator to Conduct Research**  | **True** | **False** |
| 1. The research was not solicited or influenced by LivaNova and, if approved, is not conditional in any way on any pre-existing or future business relationship between LivaNova and you or on any decision you may make in the future relating to LivaNova products.
 | [ ]  | [ ]  |
| 1. The research has clinical or scientific merit and provides valid scientific data.
 | [ ]  | [ ]  |
| 1. The study budget requested is fair and is sufficient to achieve the objectives, methodology, and timelines.
 | [ ]  | [ ]  |
| 1. You (the Investigator) in the conduct of the Study will adhere to all relevant standards including Good Clinical Practice, Good Pharmacovigilance Practice, obtaining Institutional Review Board /Ethics Committee approval, patient consent.
 | [ ]  | [ ]  |
| 1. You (the Investigator) agree that the study will be published in line with the agreed publication plan.
 | [ ]  | [ ]  |
| 1. You (the Investigator) will sign an IIR agreement prior to start of the study.
 | [ ]  | [ ]  |
| 1. You (the Investigator) are qualified through education, training, and experience to properly conduct the research and have the appropriate resources in place in order to properly conduct the research with no additional assistance from LivaNova.
 | [ ]  | [ ]  |
| 1. There is no Institution patented (filed/unfiled) technology required for the study.
 | [ ]  | [ ]  |
| **Condition of Submission:** In submitting this information, you (the investigator) attest to having authorization to do so from any other originator of this information. It is necessary within LivaNova to refer requests for IIRs to a number of different persons within the company in order to determine the level of interest for each proposal. LivaNova has no intention of publicizing a submission; however, LivaNova will not assume responsibility for keeping a submission confidential. Therefore, in submitting this request, the submitter attests that all of the submitted materials are non-confidential, none of the submitted materials contains markings of confidentiality, and LivaNova will treat all submitted materials as non-confidential. The rights of the originator(s) and submitter will be only those that are given under patent laws and/or written contract(s) to which the originator(s), the submitter, and LivaNova mutually agree. |
| **Investigator Signature** |  | **Date:** |

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| **Section 4. Study Proposal**  |
| **Title** |  |
| **Device(s) to be used (include model)** |  |
| **Approved Indication(s) for Use (IFU) (according to local labeling)** |  |
| **Will the device use be consistent with the approved IFU?**  | [ ]  Yes[ ]  No (if no, please specify): |
| **Study Design** *(select all that apply)* | [ ]  Prospective[ ]  Retrospective[ ]  Pre-Clinical[ ]  Bench[ ]  Data Sharing Request[ ]  Other: | [ ]  Registry[ ]  Cohort[ ]  Case-Series[ ]  Randomized[ ]  Controlled[ ]  Blinded | [ ]  Single Center[ ]  Multi-Center # of sites: List of Countries: |
| **Has the research proposal been *reviewed and approved* by an Institutional Review Board (IRB) or Ethics Committee (EC)?** | [ ]  Yes. *Please enclose a copy of the IRB/EC approval.* [ ]  No. *Please provide the plan to obtain EC/IRB approval or specify why this is not required:* Name of IRB/EC:  |
| **Background***Provide the scientific rationale for the proposed research*  |  |
| **Research Objectives***Provide a detailed description of the aims and objectives of the study* |  |
| **Patient Population***Provide key inclusion and exclusion criteria*  |  |
| **Clinical Sites and Recruitment Strategy** | *List all sites to be activated:**Explain the proposed recruitment strategy:**What is the anticipated number of subjects that can be screened per month?* *What is the anticipated number of subjects that can be enrolled per month?**Does the institution have any trials with similar enrollment criteria currently ongoing or planned?* [ ]  No [ ]  Yes (if yes, please specify): |
| **Primary and Secondary Endpoints***List all primary and secondary endpoints including timepoints for evaluation.*  |  |
| **Follow-up Visit Schedule***Provide the purpose of and frequency of follow-up visits*  |  |
| **Statistical Methods and Sample Size***Provide the proposed sample size and its justification as well as the analysis method of key endpoints* |  |
| **Key Study Metrics** *Provide target dates for the following metrics* | Start Date:Protocol and Statistical Analysis Plan Approved: IRB/EC Approval:First Patient Enrolled:Last Patient Enrolled:Last Patient Follow-up:Final Report Suitable for Publication: |
| **Publication Plan***Select all that apply* | [ ]  Manuscript, Number anticipated:\_\_\_Topic(s): Target Journal(s): Target Conference(s): Timeline for Publication(s):[ ]  Abstract, Number anticipated:\_\_\_Topic(s): Target Journal(s): Target Conference(s): Timeline for Publication(s):[ ]  Poster Presentation, Number anticipated:\_\_\_Topic(s): Target Journal(s): Target Conference(s): Timeline for Publication(s):[ ]  Other, Number anticipated:\_\_\_Topic(s): Target Journal(s): Target Conference(s):Timeline for Publication(s): |
| ***Note: Investigator must provide a copy of any planned publications (abstract, manuscript, presentation, book chapter, etc.) to LivaNova for review at least 30 days in advance of the submission.*** |

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| **Section 5. Requested Support** |
| [ ]  **Funds\*** | Total amount requested: |
| [ ]  **Medical Devices** | Specify number and type:  |
| [ ]  **Equipment** | Specify number and type:  |
| [ ]  **Services** | Specify services needed, include estimated amount of time required:  |
| [ ]  **Other** | Specify:  |
| ***\*Please complete Section 6. to itemize all study costs. All costs should include any applicable overhead and are subject to Fair Market Value assessment.*** |

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| **Section 6. Itemized Budget** | **Details** | **Budget** | **Total** |
| **Subject-Related Costs***Specify cost of study related procedures by follow-up visit.*  |  |  |  |
| **Study Personnel Labor***Specify each function and estimated time required.*  | Function (% Time): Function (% Time): Function (% Time):  |  |  |
| **IRB/EC Review Fees** |  |  |  |
| **Study-Related Equipment**  |  |  |  |
| **Publication Costs** |  |  |  |
| **Other:**  |  |  |  |
| **Other:** |  |  |  |
| **Other:** |  |  |  |
| **Total Amount Requested (USD)** |  |  |

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| **Section 7. Milestone Payments** | **Description** | **Amount****(USD)** | **Projected****Date** |
| *Milestone 1* | [Execution of Contract] |  |  |
| *Milestone 2* | [Protocol and Statistical Analysis Plan Approved] |  |  |
| *Milestone 3* | [EC/IRB Approval, First Patient Enrolled] |  |  |
| *Milestone 4* | [50% Patients Enrolled] |  |  |
| *Milestone 5* | [Last Patient Enrolled] |  |  |
| *Milestone 6* | [Final Study Report suitable for Publication] |  |  |
| ***The number of milestones and descriptions can be modified based on the type of research project.***  |