**ABIOMED ACADEMIC RESEARCH GRANT PROPOSAL TEMPLATE**

# Where will the research be conducted?

|  |  |  |
| --- | --- | --- |
| USA | Canada | Other, specify country: |
| Europe | Japan |  |

# Study Type (please check all that apply):

**Clinical study**

Observational/Registry

Single arm interventional

Randomized controlled

**Pre-clinical**

In vivo, indicate animal model to be used: \_\_\_\_\_\_\_\_\_\_\_\_

In vitro

In silico

Other (please describe): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

# Investigator and Contact information.

Name:

Position:

Department:

Institution:

Address:

Phone:

Email:

# Name of proposed study (limit 150 characters):

# Study Objective (limit 200 words):

|  |
| --- |
|  |

# Background & Rationale (limit 500 words): Provide a general background and describe how the proposed study will impact:

a) The global scientific knowledge and community

**and**

b) Clinical care of patients requiring Mechanical Circulatory Support

(NOTE: If Clinical, please include details related to gender, race, and/or ethnicity when describing the patient population affected by the disease/condition of interest)

# Study Design (6 pages maximum, all subsections must be addressed):

## Study Population (Human studies only). Please include a brief description of how the eligibility criteria will facilitate (or will not hinder) recruitment of a study population that accurately reflects the patient population typically affected by the disease/condition being studied with regard to gender, race, and/or ethnicity.

## Study Hypothesis

## Study protocol and methods

1. **Study methods** – must include references to existing methods to demonstrate capabilities of study site(s) and investigator(s) to execute the proposed research
2. An illustration of your study design is required (please refer to example 1 below)
3. **Brief data plan**:
   1. Study endpoints, including specific primary and secondary endpoints
   2. Major data elements and source
   3. Data collection methods and processing
4. Discussion of regulatory requirements, ie. IACUC for pre-clinical, IRB or IDE for clinical
5. **Anticipated study duration**
6. **Statistical Analysis Plan**, including:
   1. Statistical rationale, including rationale for sample size (ie. power calculations).
   2. Estimate size for the experimental and control or comparator groups.
   3. Data analysis strategy (ANOVA, Chi-squared, etc.).

## Preliminary Data – Reference any previous relevant data or previously executed study from within your research group (Applications not including preliminary data will not be considered. If inapplicable, please explain why)

## 

## Expected Results, including interpretation and importance of data. Consider what results and project outputs will be clinically relevant and of interest to Abiomed. (limit 200 words):

## Study limitations and alternative strategies or future directions if expected results are not obtained. (limit 200 words):

## Expected Deliverables (Including but not limited to: Manuscripts, presentations, and potential Intellectual property)

# Total Budget (indicate currency type):

|  |
| --- |
| Or, check box if only equipment is being requested: |

***Example #1 Flow diagram*** *(e.g., randomized controlled trial) (Credit: NIH/FDA Clinical Protocol Template)*

Prior to

Total N: Obtain informed consent. Screen potential participants by inclusion and exclusion criteria; obtain history, document.

Enrollment

Randomize

Perform baseline assessments.

List specimens to be collected, examinations, imaging, questionnaires to be completed, etc.

Visit 1

Time Point

Visit 2

Study intervention

Time Point

Follow-up assessments of study endpoints and safety

List specimens to be collected, examinations, imaging, questionnaires to be completed, etc.

Visit 3

Time Point

Follow-up assessments of study endpoints and safety

List specimens to be collected, examinations, imaging, questionnaires to be completed, etc.

Visit 4

Time Point

**Final Assessments**

List analyses to be performed

Visit X

Time Point