



Reference: _____

INVESTIGATOR-INITIATED STUDY RESEARCH GRANT APPLICATION FORM

Instructions: This application form is for **Investigator-Initiated Study Research Grants** and NOT for General Research Grants, Educational Research Grants, Charitable Contributions/Donations, or Commercial Sponsorships. An Investigator-Initiated Study Research Grant is support (e.g., funding or product) for clinical studies initiated, developed, designed, and managed by a qualified sponsor who assumes sole responsibility for conduct and management of the study. Applications must be received at least **sixty (60)** prior to the event occurring for consideration. Also, please note that your application must be submitted with all required documents (see the "Required Documentation" section of this form). **Incomplete applications and/or missing or incomplete required documents will cause delays and may result in a denial of your application.**

Applications are accepted throughout the year. Please submit your application by

email to grants@terumoortic.com

For any questions, please contact grants@terumoortic.com

A reference number will be assigned to each application and should be referenced in any interaction related to the application.

7. Are any of the requesting organization's owners, officers, directors, or managers (current or former) a Government Official ("GO") or a Family Member of a GO (Y/N)?
8. Do any of the requesting organization's owners, officers, directors, or managers (current or former) have a business relationship with a GO or a government entity, which has decision-making authority or official influence over Terumo Aortic's business activities (Y/N)?
9. To your knowledge, are there any actual or potential conflicts of interest between the requesting organization and Terumo Aortic (e.g., are any representatives of the requesting organization related to a Terumo Aortic employee) (Y/N)?
10. Within the past 5 years, has the requesting organization, or any of its owners, officers, directors, employees, or sub-contractors, been the subject of any government investigation or proceeding involving fraud or corruption (e.g., bribery, money laundering, or other corrupt practices) (Y/N)?

If you answered "Yes" to 9 and/or 10 above, please explain the potential conflict and/or the government investigation/proceeding:

Parent Organization Information

Is the requesting organization part of a larger organization (Y/N)? If yes, please provide the following information:

Parent Organization Legal Name: _____

Parent Organization Address: _____

City: _____ State: _____ Zip: _____

Parent Organization Federal Tax ID Number (for U.S. entities): _____

Parent Organization Chapter/Branch/Department: _____



Prior Funding

Has the requesting organization ever received funding from Terumo Aortic (Y/N)? _____ If yes, please provide the following information:

Year when funding was provided:

Amount of previous funding (indicate currency):

Type of previous funding:

Additional Information

Has the requesting organization discussed this request with any Terumo Aortic employee (Y/N)?

Has anyone from Terumo Aortic assisted with the preparation of this request (Y/N)?

Has a Terumo Aortic employee promised support for the requesting organization (Y/N)?

STUDY PROPOSAL_

General Information

Study Title:

Short Title:

Primary Terumo Aortic Product:

Therapeutic Area(s) to be Studied:

Consistent with the product's instructions for use?

Type of Support (i.e., funding, funding and product, product only):

Abstract (please provide a brief summary of your proposal, including the overall goal, target population, methods, and assessment):

Project Lead/Principal Investigator (PI) (note: if there is a co-investigator, please also provide their information)

PI Full Name:

PI Email Address:

PI Current Title/Position:

Is the PI a US-licensed physician (Y/N)?

PI Address:

City:

State/Province:

ZIP/Postal Code:

Country:

PI Specialty / Field of Expertise: _____

PI Primary Degree: _____

Institution and Location of Primary Degree: _____

Date of Completion: _____

Field of Study: _____

PI Secondary Degree (Optional): _____

Institution and Location of Secondary Degree: _____

Date of Completion: _____

Field of Study: _____

Site Information

Site Type: _____ Institution Name: _____

Institution Type: _____

Website: _____

Address: _____

City: _____ State/Province: _____

ZIP/Postal Code: _____ Country: _____

Primary Site Contact: _____

Title/Position: _____

Email Address: _____ Telephone Number: _____

Fax Number: _____

Multi-Site Study (Y/N)? _____ If yes, how many sites? _____

How many countries? _____

Proposal Details

Number of Subjects: _____

Anticipated Timing of Contract Execution to Study Start (in months): _____

Proposed Length of Study (in months): _____

Anticipated Timing of Study End to Final Study Report (FSR) (in months): _____

Has the study been submitted to the administrative authority for approval/authorization (Y/N)?

Has the study been approved/authorized by the administrative authority (Y/N)? If yes, when?

Trial Design(s)/Model(s):

Study Phase(s):

Overview/Hypothesis:

Background/Rationale:

Scientific Summary

Primary Objectives/Endpoints:

Secondary Objectives/Endpoints

Inclusion Criteria:

Exclusion Criteria:

Population:

Sample Size/Statistical Power:

References:

Protocol

Please attach the Study Protocol to this application form.

Requested Funding

Please attach the Study Budget to this application form.

Requested Currency:

Overhead Percent:

Total Direct Costs with Overhead:

Total Indirect Costs:

Total Study Costs:

Amount Requested:

Please list all other sources of funding (grants, additional supporters, etc.)

Budget Comments:

Planned Results/Publications

Target date to provide results to Terumo Aortic:

Will you be publishing the results of the study (Y/N)?

If yes, please answer the following questions:

Result type (e.g., abstract, final report, manuscript, poster, etc.):

Date of first anticipated publication
and Planned results notes::

If no, please provide your reason(s) for not publishing.

PRODUCT SUPPORT

Are you seeking support in the form of product from Terumo Aortic for any of the activity described above?	If Yes, a Product Support Form shall be attached to this application form
Are you requesting Terumo Aortic to loan a Simulator(s)?	If Yes, please describe
Are you requesting a Model(s)?	If Yes, please describe

REQUIRED DOCUMENTATION

W-9 Form (current) (or comparable form for applicants outside the United States)	
List of Members of the Requesting Organization's Board of Directors (names and titles)	If applicable
Request Letter	
IRS Letter of Determination (for U.S. entities)	If applicable
Study Protocol	
Study Budget	
Copy of the submission or approval of the study by the administrative authority	If applicable
Organization Governing Document (e.g., Organization's Articles of Incorporation)	

PAYMENT

Is the Payee address the same as the Organization address?	If No, please indicate the address for forwarding financial awards (checks):
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CERTIFICATIONS

Please read the following certifications carefully. You must certify the following before you can submit your request to Terumo Aortic for consideration. By signing this application form, you acknowledge that the following statements are true and correct.

You certify that you are authorized to submit an application for financial support from Terumo Aortic and provide information in an application on behalf of the requesting organization and any partner organization(s), and you affirm that all responses and information provided in this application are truthful, accurate, and complete.

You certify that all materials submitted are non-confidential (regardless of any markings on the documents, including, but not limited to, confidentiality, privilege, trademark, or copyright). By submitting your materials to Terumo Aortic for review, you expressly consent to the circulation, distribution, and use of the documents and information by Terumo Aortic as Terumo Aortic in its sole discretion deems reasonable and appropriate, including, but not limited to, in considering the request for financial support.

You certify that Terumo Aortic has had no involvement in the creation or development of this project or the completion of this application form.

You certify that, if approved, the source of all support from Terumo Aortic must be disclosed in all publications and presentations.

You certify that neither this request nor the requested funding is conditioned on, related to, or intended as an inducement or reward for: (a) any pre-existing or future business relationship with Terumo Aortic; or (b) any business or other decision relating to Terumo Aortic or its products (including regulatory approval, coverage and pricing determinations, tenders, or formulary status decisions).

You certify that neither you nor your organization's directors, trustees, and/or anyone who will be involved in the project(s) that will be funded by this grant are on the OIG exclusion list or FDA debarment list.

Please note, if the grant request is approved, you will be required to sign a contract that includes additional terms and conditions as they relate to the execution of the request consistent with all applicable law and Terumo Aortic policy.

Name (Please print)

Title

Authorized Signature

Date

Organization Name

Date