

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 **ninety (90) days** 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:

EMEA: GrantCommittee.Emea@microvention.com.
All others: MVGrantCommittee@Microvention.com.

For any questions, contact MVGrantCommittee@Microvention.com or GrantCommittee.Emea@microvention.com.

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

REQUESTING ORGANIZATION INFORMATION

Date: ____/____/____	Name of Organization/Institution: _____
Organization Contact: _____	Title: _____
Address: _____	
City: _____	State/Province: _____
ZIP/Postal Code: _____	Country: _____
Telephone Number: _____	Email Address: _____
Website: _____	
Federal Tax ID Number (for U.S. entities): _____	
Tax Status: _____	
Year of Establishment: _____	Organization Type: _____
Annual Operation Budget: _____	
Is the organization (or parent organization) on the United States Centers for Medicare & Medicaid Services (CMS) Open Payments List of Teaching Hospitals (for U.S. entities) (Y/N)? _____	
Do you have a Board of Directors (Y/N)? _____ If yes, please provide a list all Members of the Board of Directors (names and titles).	
1. Is the requesting organization comprised entirely of, owned by, or controlled by Health Care Professionals ("HCPs") (Y/N)? _____	
2. Is the requesting organization a Health Care Organization ("HCO") or physician's practice (Y/N)? _____	

3. Is a MicroVention employee on the Board of Directors of the requesting organization (Y/N)? _____
4. Does a MicroVention employee have a controlling position in the requesting organization (Y/N)? _____
5. Is the requesting organization a customer of MicroVention (e.g., can it purchase, prescribe, or influence the use of any MicroVention products) (Y/N)? _____
6. Is the requesting organization a government entity (Y/N)? _____
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 MicroVention's business activities (Y/N)? _____
9. To your knowledge, are there any actual or potential conflicts of interest between the requesting organization and MicroVention (e.g., are any representatives of the requesting organization related to a MicroVention 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 MicroVention (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 MicroVention employee (Y/N)? _____

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

Has a MicroVention employee promised support for the requesting organization (Y/N)? _____

STUDY PROPOSAL

General Information

Study Title: _____

Short Title: _____

Primary MicroVention 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)? _____ If yes, NPI: _____

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 MicroVention: _____

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: _____

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 MicroVention for any of the activity described above?	
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(If Yes, a Product Support Form shall be attached to this application form)	
Are you requesting MicroVention 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 (Y/N)?	
If No, please indicate the address for forwarding financial awards (checks):	

CERTIFICATIONS

Please read the following certifications carefully. You must certify the following before you can submit your request to MicroVention 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 MicroVention 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 MicroVention for review, you expressly consent to the circulation, distribution, and use of the documents and information by MicroVention as MicroVention in its sole discretion deems reasonable and appropriate, including, but not limited to, in considering the request for financial support.

You certify that MicroVention 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 MicroVention 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 MicroVention; or (b) any



business or other decision relating to MicroVention 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 MicroVention policy.

Name (Please print)

Title

Authorized Signature

Date

Organization Name

Date