

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 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:

- MVGrantCommittee@microvention.com

For any questions, please contact the MicroVention Grant Liaison Manager, Linn Pearce: linn.pearce@microvention.com.

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 Operating Budget: _____	
Is the organization (or parent organization) on the United States Centers for Medicare & Medicaid Services (CMS) Open Payments List of Teaching Hospitals (Y/N)? _____	
Do you have a Board of Directors (Y/N)? _____ If yes, please provide a list all Members of the Board of Directors.	
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 (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: _____

Type of previous funding: _____

Additional Information

Has the requesting organization discussed this grant request with any MicroVention employee (Y/N)? _____

Has anyone from MicroVention assisted with the preparation of this grant 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)? _____

PI Address: _____

City: _____ State/Province: _____

ZIP/Postal Code: _____ Country: _____

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: _____

Contract Execution to Study Start (in months): _____

Length of Study (in months): _____

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

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?	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) (Y/N)?	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	If applicable
IRS Letter of Determination	If applicable
Study Protocol	
Study Budget	
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):
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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

GLOSSARY OF DEFINED TERMS

Family Member of a Government Official	<p>Any spouse, partner, parent, grandparent, sibling, child, niece, nephew, aunt, uncle, cousin, or any other individual sharing the same household with a Government Official.</p>
Government Entity	<p>Any government-, state-, or public-owned or operated (in whole or in part) department, agency, body, authority, organization, or instrumentality thereof (including public hospitals and public universities).</p>
Government Official (“GO”)	<p>Any individual who works for a government agency, entity, or institution. This includes any individual that is employed by an organization that is government owned or controlled. This also includes associates of global non-profit organizations, which the U.S. Foreign Corrupt Practices Act refers to as “public international organizations,” like the United Nations, the Red Cross, or the World Bank.</p> <p>For clarity, the following individuals are considered Government Officials:</p> <ul style="list-style-type: none"> • Any elected or appointed official (e.g., Minister of Health, elected politician, any member of a royal family); • Any person who works for, or on behalf of, a Government Official, government agency, or an enterprise performing a governmental function (e.g., customs officer, tax authority, police officer, military personnel); • Any person who works for, or on behalf of, a state-owned or controlled entity (e.g., an HCP employed by the Ministry of Health or that works for government-owned hospitals or clinics); • Any political party officer or candidate for public office (e.g., a candidate running for governor or mayor); • Any person acting for, or on behalf of, a public international organization (e.g., the United Nations, the Red Cross, or International Monetary Fund); • Any person who is considered a Government Official under local law; or • Any Family Member of a Government Official, including any spouse, partner, parent, grandparent, sibling, child, niece, nephew, aunt, uncle, cousin, or any other individual sharing the same household with a Government Official.
Health Care Professional (“HCP”)	<p>Any person or entity (a) authorized or licensed to provide health care services or items to patients or (b) who is involved in the decision to purchase, prescribe, order, or recommend a medical device/technology. This term includes individual clinicians (for example, physicians, nurses, and pharmacists, among others), provider entities (for example, hospitals and ambulatory surgical centers), and administrative personnel at provider entities (for example, hospital purchasing agents). This term does not include Health Care Professionals who are bona fide associates of a Company, while acting in that capacity.</p>
Investigator-Initiated Study Research Grant	<p>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.</p>
MicroVention (“MVI”)	<p>MicroVention, Inc. and its global affiliates.</p>