Investigator-Initiated Research Request Application

Arthrex Inc. 1370 Creekside Boulevard • Naples, Florida 34108

Arthrex provides funding for independent research activities that are aligned with our strategic initiatives to help surgeons treat their patients better. No direct payments will be made to an individual or health care professional. Awarded investigator-initiated research requests are provided without any conditions of product use or contingency upon any commitment to purchase, use, or recommend Arthrex products either in the past or the future.

Submission of Research Requests

- Only investigator-initiated research request applications using the form found on www.arthrex.com and submitted via e-mail to researchgrants@arthrex.com will be considered for review.
- Incomplete applications will not be reviewed.
- Completed research requests must be submitted at least 90 days before the start date of the intended research to allow for placement on the Arthrex Global Grants Committee agenda and internal processing.
- All US-based requestors must submit a completed and signed W-9 form including the Federal Tax ID number.
- To expedite the support process, requests for Arthrex products MUST include all part numbers and quantities to be considered for the review process. Please refer to the Arthrex website for detailed product codes and sizing information.
- The legal party name in Part 1 must accurately reflect what will be listed on the contractual agreement.
- For clinical studies, a protocol must be submitted prior to final approval.

Global Grants Committee Application Review

- All research requests will be reviewed by the Arthrex Global Grants Committee. This process has been approved by the Arthrex Risk Management and Compliance Department. Decisions will be based on objective criteria such as, but not limited to, clinical relevance, scientific impact, methodological approach, proposed budget, study timeline, and overall compliance.
- The Arthrex Global Grants Committee will make every effort to review research request applications within 12 weeks of submission and acceptance as complete.

Research Request Application Decision

- The Arthrex Global Grants Committee will approve, suggest modifications, or decline the research request.
- An email notification regarding the decision will be sent after the Global Grants Committee meeting.
- All approved grant recipients are required to complete contractual agreement documentation. This documentation must be fully executed by all required parties within 10 business days to proceed with monetary or product support.
- Requests for additional monetary or product support after a project has been formally approved must go through review by the Global Grants Committee at their next meeting for decision and are not guaranteed for approval.

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Part 1: Institution Contact Information

Requester (Contact):	Title:	Department:
Email:	Phone Number:	Institution:
Street Address:	City, State:	ZIP:

Principal Investigator (if different from above):	Department:	
Email:	Phone Number:	Institution:
Street Address:	City, State:	ZIP:

Legal Party Name for Agreement:	US Federal Tax ID # *(for US-requestors only):*	Attention Line:
Street Address:	City, State:	ZIP:

Co-investigator(s) and Sub-investigators
(individuals who have a major role in the research at the site and at additional sites)

Name:	Department:	Organization:	Different Site and Contract
			☐
			☐
			☐

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Part 2: Research Proposal

Full Research Title

Choose a descriptive research title that reveals the key elements of the planned study.

Study Objective

Specify the primary and secondary objectives/hypotheses of the planned study.

Materials and Methods

Describe the planned study design, taking into consideration the setting in which the data will be collected, sample size, duration of the study, and statistical analyses.

Clinical studies

- Study design (eg, prospective, retrospective, observational, etc.)
- Planned recruitment period
- Patient eligibility criteria
- All visit time points (eg, pre-op; surgery/treatment; 1, 3, 6, 12 month[s] post-op)
- Intervention(s)/treatment(s), comparison group(s) (if any)

Laboratory studies (biomechanical, in vitro, etc.)

- Detailed test setup
- Comparison of groups (if any)
- Clinical relevance (define acceptance criteria)

Clinical Outcome Measures or Data Metrics for Laboratory Testing State primary and secondary outcomes.
Expected Outcome Indicate the expected outcome. This may be based on previously collected data and/or publications.
Related Literature If applicable, list relevant publications related to the planned study.
Electronic Data Capture (if applicable)
Do you plan to capture your clinical outcomes data electronically? Yes No If yes, select one: ☐ Surgical Outcomes System (SOS) www.surgicaloutcomesystem.com Other

Research Timeline

Please complete the expected dates for the following study milestones:

Project Initiation Date:	Project Completion Date:

Milestones	Deliverable	Date (MM/YYY)
M1	Signed agreement (and ethical approval when required)	
M2	Study 25% complete	
M3	Study 75% complete	
M4	Final report	

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Part 3: Itemized Budget

Research Request (select all that apply)**:**
☐ Monetary (requested from Arthrex, more details below)
☐ Product (more details in Part 4)
☐ Access to Arthrex Orthopedic Research Facilities and Staff (more details in Part 5)

Itemized Budget Requested From Arthrex

This may include clinical study-specific efforts that are not standard of care or reimbursed. For laboratory studies, this may include required materials. Do not list Arthrex products in this area. For multiple sites, attached a separate itemized budget as formatted below for each site.

Item:	**Cost:**
Additional costs if applicable (eg, VAT, facility overhead, etc.):	
Total Cost (in local currency):	

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Part 4: Products and Instrumentation Used in the Study

- Arthrex products **MUST** include all part numbers and quantities to be considered for the review process. Refer to the Arthrex website for product information: www.arthrex.com.
- Please use one line per item requested.

Part Number (AR-####):	Name:	Quantity (each):	Request at No Charge
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Part 5: Requested Support From Arthrex Orthopedic Research Facilities and Staff

Requested Support:	Description: