



Investigator-Initiated Research Grant Application Form

Instructions:

Fill out all sections of this application form. Write “N/A” if question or section does not apply to your research proposal. Return this application with copies of the following:

- ☐ Research protocol
- ☐ Detailed budget
- ☐ Timeline
- ☐ Current CV of Principal Investigator

to research@paragon28.com when complete. Incomplete applications will not be considered. Please direct all questions to research@paragon28.com.

SECTION 1: RESEARCH DETAILS AND CONTACT INFORMATION

| | |
|---|--|
| Research Title: | |
| Requestor and Title: | |
| Contact Person (if different from requestor): | |
| Email: | |
| Phone: | |
| Institution: | |
| Address: | |
| | |
| Principal Investigator: | |
| Email: | |
| Phone: | |
| Institution: | |
| Address: | |
| | |
| Grant Recipient Organization: | |
| Federal Tax ID #: | |
| Address: | |
| | |
| Relevant IRB (if applicable): | |

SECTION 2: FUNDING INFORMATION (if applicable)

| Accounts Receivable Contact Information | |
|---|--|
| Name: | |
| Email: | |
| ACH Information | |
| Name of Bank: | |
| Routing Number: | |
| Account Number: | |

SECTION 3: RESEARCH DETAILS

Purpose:

Hypothesis:

Unsolved research question(s) this research aims to solve:

Clinical relevance:

Materials and Methods:

Level of Evidence:

Expected Outcome:

Preliminary Results (if available):

Related Literature (list of relevant studies from the past 5 years):

Principal Investigator:

Co-Investigator(s) (name, organization, department):

Outcome Measurements (if applicable)

System of measurement (i.e. Radiographic fusion, CT scan, etc.):

Scoring system (AOFAS Hindfoot Score, PROMIS Score, etc.):

Research Timeline Highlights

Please attach a detailed timeline to this application.

Project start date:

Project completion date:

Barriers to starting project:

Milestones (e.g. data gathering points, intended project updates):

Possible project delays:

Publication Intentions:

Poster Abstract Submission:

Journal Publication Submission:

Proposed Author(s):

SECTION 4: BUDGET

Grant request (check all that apply):

- ☐ Monetary
- ☐ Product
- ☐ Access to Paragon 28 Facilities and/or Staff

Please attach a detailed budget to this application. Budget details should include but are not limited to: study related costs, personnel costs, diagnostic fees and services, data management expenses, IRB fees (review and yearly), publication costs, equipment/supply expenses, cadaveric specimens, overhead % fee, *etc.* If any other sources of funding are being applied to your study, please specify both the organization and the amount of support you anticipate receiving. A total cost should be calculated and specified.

If product is being requested, please do not include those costs in your budget. Include product needs in the table below.

If access to Paragon 28 facilities and/or staff is needed, specify with detail what those needs are in a separate document and include it with your application.

SECTION 5: REQUESTED PRODUCTS AND REQUIRED INSTRUMENTATION

| Product Name | Size | Right/Left | Quantity |
|--------------|------|------------|----------|
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* Please attach additional sheet if more information is necessary on requested products and instrumentation

Paragon 28 Investigator-Initiated Research Grant Guidelines

Paragon 28 strives to advance the science of foot and ankle surgery and improve clinical outcomes through meaningful and unbiased research. Funding is provided to those requests that are aligned with our company's mission and strategic objectives while serving the purpose of providing scientific and clinical information to improve patient care and outcomes.

Completion of this application along with submission of a research protocol, detailed budget, timeline, and CV are required to be considered for a Paragon 28 Investigator-Initiated Research grant. Incomplete applications will not be considered and may delay the decision process.

All requests will be reviewed objectively by the Paragon 28 Research and Grants Committee, which is comprised of members of senior management, clinical affairs, and compliance. The Paragon 28 Research and Grants Committee meets quarterly. It is recommended that submissions for research proposals be provided to Paragon 28 at least three months prior to initiating research to ensure enough time to complete the review, and, if accepted, complete the research contract and delivery of approved support.

Consistent with the AdvaMed Code of Ethics and Paragon 28 policy, decisions will be based on objective criteria, including but not limited to: alignment of the study with strategic objectives of the company, clinical significance and the effect on patient outcomes, unmet research and development needs, scientific method, timeline, budget, and compliance. In addition to these factors, and irrespective of the propriety of the request, research grant funding is contingent upon the availability of funds specifically earmarked by Paragon 28 for research-based projects.

The provision of a research grant shall not be related, directly or indirectly, to the volume or value of purchases or referrals made by or anticipated from the recipient nor shall the grant be used as an unlawful inducement. No direct payments will be made payable to individuals or healthcare professionals.

Alignment with strategic objectives of the company: Paragon 28 supports research that is aligned with our strategic research initiatives, current product offerings, and immediate pipeline of products.

Clinical significance/effect on patient outcomes: Projects that have the potential to most positively impact the foot and ankle surgical community and improve patient outcomes will receive higher consideration.

Unmet research and development needs: Paragon 28 will place greater consideration on projects that are innovative and scientifically advanced. Projects that are duplicates of current research, have already been published, or projects that can be performed in-house will not be considered. Priority will be given to projects that cannot be performed in-house, such as clinical outcomes studies.

Scientific Method: The study site must be conducive to conduct the research. Research methods including data collection and statistical plan must follow acceptable scientific methods.

Timeline: A clear timeline with realistic goals, outcome parameters, and study time points will be given higher consideration than those that do not have measurable outcomes and timelines.

Budget: Paragon 28 will assess the proposed budget for the research project to ensure that line items comport with Fair Market Value. Paragon 28 may award a lesser amount than requested.

Compliance: Requests must be consistent with Paragon 28 policies and the AdvaMed Code of Ethics on Interactions with Health Care Professionals. If a compliance violation is observed or detected, the research request will be rejected in its entirety.