

Paragon²⁸[®]

a  ZIMMER BIOMET company

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 to **research@paragon28.com** when complete:

- ☐ Research Protocol
- ☐ Current CV of Principal Investigator
- ☐ Budget (with justifications)
- ☐ Timeline
- ☐ List of Requested Products / Instrumentation (if applicable)

Incomplete applications will not be considered.

Please direct all questions to **research@paragon28.com**.

SECTION 1: INVESTIGATOR & STUDY CONTACT

Principal Investigator (PI):

Title:

Institution:

Email:

Phone:

Alternate Primary Contact (if different than PI):

Title:

Email:

Phone:

Institution Address:

SECTION 2: STUDY OVERVIEW

Title of Research Project:

Brief Study Description (1-2 sentences):

Primary Objective:

Secondary Objective:

Paragon28 Product(s) to be Studied:

SECTION 3: STUDY DESIGN DETAILS

Study Type:

- ☐ Clinical
- ☐ Scientific

SECTION 3.1: STUDY DESIGN DETAILS (CLINICAL)

Study Type (select all that apply):

- ☐ Interventional (e.g., treatment, procedure, device)
- ☐ Observational (e.g., registry, case series)
- ☐ Retrospective
- ☐ Prospective
- ☐ Other:

Primary Hypothesis or Clinical Question:

Sample Size (with justification):

Outcome Measures:

- ☐ PROMs
- ☐ Radiographic
- ☐ Clinical
- ☐ Economic
- ☐ Other:

Data Collection Timepoints (check all that apply):

- ☐ Pre-op
- ☐ Intra-op
- ☐ 2-wk
- ☐ 6-wk
- ☐ 3-mo
- ☐ 6-mo
- ☐ 1-yr
- ☐ 2-yr
- ☐ Other:

IRB Required:

- ☐ Yes
- ☐ No
- If no, why?

SECTION 3.2: STUDY DESIGN DETAILS (SCIENTIFIC)

Study Type:

- ☐ Bench
- ☐ Cadaveric
- ☐ Computational
- ☐ Other:

Scientific Hypothesis or Research Objective:

Sample Size (with justification):

IRB Required:

- ☐ Yes
- ☐ No
- If no, why?

SECTION 4: VALUE & ALIGNMENT

Why is this research valuable to Paragon 28, a Zimmer Biomet company?

Why is this research valuable to your peers or clinical community?

Is this application related to a request for protocol? If yes, add relevant topics of interest:

Expected Publications / Dissemination Plan:

SECTION 5: BUDGET & SUPPORT

Estimated Total Budget:

Funding Type Requested:

- ☐ Monetary
- ☐ Product
- ☐ In-kind support

Paragon 28 Investigator-Initiated Research Grant Guidelines

Paragon 28, a Zimmer Biomet Company, 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, current CV of the principal investigator, budget (with justifications), and timeline 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 one or more committees. It is recommended that submissions for research proposals be provided to Paragon 28 at least six 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 conducting 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.