



INVESTIGATOR-INITIATED RESEARCH GRANT REQUEST FORM

TITLE OF THE STUDY: _____

In accordance with Orthofix Medical, Inc. and its subsidiaries' (the "Company") Compliance Work Instruction EC1.C entitled, "Third Party Requests For Financial Support and Product Donations," this Investigator-Initiated Research Grant Request Form ("Request Form") is to be used by an organization or entity requesting a grant to support independent investigator-initiated research. **This Request Form should NOT be completed by Company Employees.**

Each completed Request Form, along with all applicable supporting documentation, must be submitted to the applicable Grant Committee for review a minimum of six (6) weeks prior to the inception of the event.

1. Date of Request: _____

2. Name of the Requesting Organization: _____

3. Name and Contact Information of Requestor: _____

4. Principal Investigator: _____

5. Organization's Identifying Number:
For US entities, Federal Tax ID Number - _____
For entities outside the US, Business
Registration Number - _____

6. Is the Organization Tax-Exempt? Yes No
If yes, attach documentation of exempt status.

7. What kind of support are you requesting from Orthofix:

a. Orthofix products, No Yes – Attach a list of Products being requested and the quantity of each item.

b. monetary support: No Yes – Currency/Amount of Funds being Requested: _____

c. Other, please specify: _____

8. What is the publication plan of the study results:

Congress (oral or poster) Journal publication Other

9. What is the main objective of the study?

10. What is the rationale of the study?

11. Please describe the study design:

- | | |
|---|--|
| <input type="checkbox"/> Prospective | <input type="checkbox"/> Retrospective |
| <input type="checkbox"/> Interventional | <input type="checkbox"/> Observational |
| <input type="checkbox"/> Single arm | <input type="checkbox"/> RCT |
| <input type="checkbox"/> Cadaver study | <input type="checkbox"/> (Bio-) Mechanical |

Other important characteristics (blinding, case controlled, etc.):

12. If other sites are involved, please list them below (Name of the Hospital/s and Principal Investigator):

13. What is the primary endpoint of the study and how will this be measured?

14. What are the secondary endpoints of the study (if any) and how will they be measured?

15. What is the patient population and what are the inclusion and exclusion criteria?

16. What is the expected overall study duration?

17. Please describe the statistics (sample size calculation, proposed post-hoc analyses; as applicable):

18. Please confirm whether the study will be executed according to the declaration of Helsinki; GCP and applicable laws.

19. Please confirm the following:

- Ethics committee approval (or similar) will be obtained before first patient enrollment
- Patients will be asked for their written informed consent prior to enrollment, if required by local law or local ethics committee.
- Orthofix products will be used according to the indications and contra-indications in the Instructions For Use leaflet

20. Attach the following required documentation:

- a. Copy of the protocol or study summary or outline;
- b. Information, including dates and amounts, regarding past grants from Orthofix;
- c. Documentation of the organization's tax-exempt status, whether under IRS Code Section 501(c)(3) or 501(c)(6), or under a similar country or state law;
- d. If requestor is a U.S. entity, a completed W-9 form which reflects the organization's Employer ID Number (EIN) (also known as a taxpayer ID number);
- e. If requestor is an entity outside of the U.S., documentation reflecting the organization's business registration number;
- f. Organization's total budget for the project, indicating percentage spent on overhead; and
- g. Organization's Data Protection Program including compliance with the Global Data Protection Regulation.

I certify that all information provided in this Request Form is accurate and complete, and I understand that consideration of this request is not conditioned upon prescribing, purchasing or recommending any Orthofix products. I certify that this grant request is related to independent investigator-initiated research and is free from influence or involvement from employees or agents of Orthofix. I understand that Orthofix may not influence or control any element of the study, including study criteria, study outcomes and publication. I further understand that only the applicable Orthofix Grant Committee in conjunction with the Company's Chief Scientific Officer, can approve a grant request and make a commitment to provide funding.

Requested By: _____
Printed Name:: _____
Date: _____

Scan and e-mail this form and all supporting documentation to Grants@Orthofix.com.