DePuy Synthes CMF People inspired™
COMPANIES OF Johnson & Johnson

REQUEST FOR PROPOSAL

General Application Completion Guidelines

Research Proposal/Protocol Submission Instructions

The Investigator must complete the application. If you have questions, please email them to DePuySynthes-RFP@its.jnj.com.

STEP 1: Complete Study Application

STEP 2: Develop a detailed research proposal/protocol, and confirm that it meets all of the requirements in the **Research Proposal/Protocol Format** section below.

STEP 3: Submit the application along with the following required documents:
- A detailed research proposal/protocol in PDF format
- Itemized study budget. Please refer to the **Study Budget Format section below for additional information**
- Copy of current CVs and current medical licenses for Investigator and Sub-Investigators

Completed documents must be received by the stipulated deadline. Any submission missing the required documents listed above will be returned to the Investigator. If the submission deadline has not passed, the Research Proposal may be re-submitted with the required documents.

Research Proposal/Protocol Format:

Total number of pages for a Research Proposal/Protocol should not exceed 10 pages. Figures in the proposal may be integrated within the text or included as a separate appendix (not included in the page limit). References may be attached on separate, additional pages and are not included in the page limit.

The Research Proposal/Protocol should include the following components:

- *Introduction or Abstract:* The introduction should orient the reviewers with respect to the sections which follow. It may be in the form of a comprehensive abstract or a more limited introduction. Any new collaborations or highly innovative aspects of the research should be briefly noted.
- *Specific Objectives and Rationale:* Aims should highlight specific hypotheses to be tested. If new techniques, new populations or new collaborations are utilized to test these hypotheses, they should be emphasized. Method(s) of data analysis should also be highlighted.
- *Background (including Preliminary Results if available), and Significance:* In addition to scientific background, the section on Significance should indicate relevance to existing treatment approaches. This section should clarify how answers to the research questions asked will impact or advance the field. This section should also include discussion of how proposed research differs from previous research in the same area of interest.
- *Research Design & Methods:* Study design should support the hypotheses or questions addressed and Methods section should be brief but sufficiently detailed to offer reviewers an indication of the feasibility and validity of the hypothesis. Weaknesses in the proposed study and how they will be addressed should be fully discussed. Statistical approaches to data analysis should be outlined where applicable.
- *Study Population and Study Procedures:* The proposal should define the study population (i.e. target demographic/medical history profile, eligibility criteria, number of study sites). Also, a description of study procedures should be included (i.e. details of the informed consent process, plan to ensure adherence to good clinical practice, projected timeline, interventions).

Data collection forms may be submitted as PDF documents as well.

Study Budget Format:

Itemized Budget costs including but not limited to the following:

- institutional overhead (if required) or research staff time spent on study related activities,
- indirect costs
- patient costs (stipends or testing requirements that are not Standard of Care),
- name(s) of ancillary personnel, role(s) on project, itemized duties and salary (if requested)

This budget should be for work to be performed, not for work already in progress, or already completed studies. The budget

should not exceed Fair Market Value (FMV) and other funding sources must be fully disclosed in the submission.

Funding may be divided among more than one Investigator but this must be reflected in the budget with clear justification.

Additional Guidelines:

An applicant must be qualified to conduct human research studies. Investigator training in human research protection is available at:
http://www.wirb.com/Pages/EducationServices.aspx

All research proposals are reviewed by Depuy Synthes through an internal panel and committee process; panel reviewers and committee members are selected from appropriate disciplines within the company. In **clinical studies**, funding is typically for the length of the study including the IRB/Ethics Committee approval process, data collection (retrospective studies) or subject enrollment and follow-up (prospective studies). DePuy Synthes reserves the right to determine the level and period of funding support the company is willing to provide which may be different from that requested by the Investigator.

Applicants who are approved for funding must submit a fully developed Research Protocol in established scientific format *prior to* execution of the Investigator Study Agreement, if not previously submitted. All approved applications will require a study agreement, based on fair market value costs and delivery of agreed milestones, to be executed with your institution before the research can be started and any funds released.

Contracts and Milestones

If an application for support for the proposed research is approved, the applicant and/or the applicant's Institution will be sent a contract (typically referred to as a Research Agreement). The terms of support and the roles and responsibilities in a **clinical** Investigator Initiated Study (IIS) will be detailed in the contract between the Company and the applicant or applicant's Institution as required by legislation.

- All required documents, including the Research Protocol, must be submitted prior to execution of the contract
- All contracts must be fully executed prior to the commencement of any support for research activities
- Unless otherwise specified, the minimum publication deliverable for a supported IIS will be a draft manuscript of publication quality
- All material support and editorial contributions by Depuy Synthes personnel will be acknowledged in any presentations or manuscripts that arise from the supported research according to the ICMJE Uniform Requirements and the requirements of the journal to which the manuscript is submitted

Study Reports

- Reports are required on an annual or more frequent basis and are due at specific times during the conduct of the research study as noted in the terms of the contract
- Investigators failing to submit required reports within the specified timeframes may be at risk of losing funding support and may be requested to return all distributed funds

Request for Proposal Application

The Request for Proposal (RFP) is a guided investigator-initiated study (IIS) conducted by an independent researcher for which DePuySynthes provides support in the form of funding and/or technical input.

This application must be completed and signed by the Investigator and submitted along with a research proposal, detailed study budget and current CV and medical license to DePuySynthes-RFP@its.jnj.com. Please complete all information as it pertains to your request. If a field is not applicable, please indicate "NA"

Any support awarded will be subject to further terms and conditions to be included in a written, fully executed Study Agreement/Contract between DePuySynthes, Investigator and/or Institution.

Investigator and Clinical Study Details

Investigator Name			
Investigator Title			
Institution's Name			
Institution's Full Address			
Phone			
Fax			
Email			
Type of Application	☐ New application	☐ Resubmission	
	☐ Amendment		
Study Title			
Study Design (Please check all that apply)	☐ Multi-center	☐ Single center	
	☐ Open label	☐ Prospective Test Group	☐ Single arm only
	☐ Blinded	☐ Prospective Control Group	
	☐ Randomized	☐ Retrospective Test Group	
	☐ Other (Specify Below):	☐ Retrospective Control Group	
	_____		

Sample Size and Individual Group Size and Characterization or Definition[1] **[1]Test Group, Control Group, Negative or Positive Control Group, Gold Standard (reference treatment), etc.**	Total Sample Size: _____ Group #1: _____ Group #2: Group #3: Group #4: (Please add additional groups if necessary)
Study Population	Please indicate the number of patients seen at institution(s) per year who may be eligible to participate in the study. ____ Anticipated patients per year Additional Comments (if any):
Subject's Study Duration	Total length of study period per subject: ____ months
Length of Overall Study	Total Anticipated Study Duration: ____ months (incl. IRB/IACUC approval, recruitment, follow-up) Estimated Subject Enrollment Rate ____ subjects/month
Study Start & End Date	Anticipated IRB Approval Date: _____ (month/year) Anticipated Start Date of Enrolment: _____ (month/year) Anticipated Date of Study Completion (Last Follow-up Visits): _____ (month/year)
Additional sources of funding	☐ Yes ☐ No If yes, please specify: _____
Additional collaborators and/or institutions involved	☐ Yes ☐ No If yes, please indicate name, title, contact information and role of each collaborator (i.e. study coordinator, research nurse, co-PIs), and institution name/address if different from that of the Investigator. Please include separate sheet if additional space is needed.

Name:	Name:
Title:	Title:
Phone:	Phone:
Email:	Email:
Institution:	Institution:
Address:	Address:
Role in Proposed Study: ☐ Co-investigator ☐ Study Coordinator ☐ Other (Specify):	Role in Proposed Study: ☐ Co-investigator ☐ Study Coordinator ☐ Other (Specify): `

Number of years of clinical trials experience	
Describe previous studies you have conducted and your role in the past 2 years	
Staff dedicated to clinical research	☐ Yes ☐ No
Access to Institution's Research office and/or services	☐ Yes ☐ No ☐ NA

Please send completed application package to DePuySynthes RFP Program:

By Email (in PDF format):
DePuySynthes-RFP@its.jnj.com

By Fax:
610-719-5102

By Mail:

DePuy Synthes
attn: DEPUY SYNTHES REQUEST FOR PROPOSAL
1302 Wrights Lane East
West Chester, PA 19380
USA

Please note that evaluation of completed applications will take 8 to 12 weeks.

Application Submission Checklist

- ☐ Completed application signed by the Investigator (required)
- ☐ Current CVs and Medical Licenses for Investigator and Sub-Investigator(s) (required)
- ☐ Research Proposal/Protocol in appropriate format (required)
- ☐ Detailed itemized study budget (required)