Research Proposal Form

Forward this completed proposal and a copy of any prepared research protocol/plan and CV(s) to Acumed Clinical Research Department, 5885 NW Cornelius Pass Rd, Hillsboro, Oregon 97124 or email at clinicalresearch@acumed.net.

Title of Research Proposal				
Investigator *with leading oversight*	Name		Title	
	Direct phone		Email	
Subinvestigators ☐ Not Applicable	Name		Email	
	Name		Email	
	Name		Email	

Please provide CVs for the listed Investigator and each Subinvestigator/s

Facility and Personnel

Institution Address *where research will be conducted*	Name			
	Address			
	Phone		Fax	
Additional Locations *where research will be conducted* ☐ Not Applicable	Name			
	Address			
	Phone		Fax	
Third-party facility *Outsourced facilities where additional research may be conducted* ☐ Not Applicable	Name			
	Address			
	Phone		Fax	
Research Coordinator ☐ Not Applicable	Name		Title	
	Direct phone		email	
Research Assistant ☐ Not Applicable	Name		Title	
	Direct phone		email	

Device Description

Product Description	Device:	
	Device:	
	Device:	
	Device:	
	Device:	
Indication for Use *for this research*		

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Type of Research	Nonclinical ☐	*In vivo* or *in vitro* mechanical, cadaveric, or animal research	
	Case Study/Series ☐	Descriptive research involving individual/s with a known indication	
	Clinical Study ☐	○ Post-Market	○ Pre-Market
		○ Prospective	○ Retrospective ○ Retro-Prospective
		○ Single Center	○ Multi-center
		○ Control	○ Uncontrolled
		○ Randomized	○ Non-randomized
		○ Open	○ Single Blind
		○ Additional Information:	

Will research involve **off-label use** of products listed?	Yes ○ No ○	Acumed cannot support clinical research outside the cleared or approved labeling

Non-Clinical Research Plan

(Go to next page to submit Clinical Study)

Purpose *Reason for the research.*	
Hypothesis	
Primary Outcome	
Secondary Outcome/s	
Methods *Provide detailed description of test methodology*	
Number & Description of Test Articles	
Samples Size *Provide statistical rationale*	
Statistical Analysis *Specify how each outcome measure listed above will be analyzed*	
Clinical Significance	

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Background / Summary of publication history on treatment of interest		
Duration of Research	Estimated Start Date of Research	
	Duration of Research (in months)	
	Estimated End Date of Research	
	Estimated date of final deliverable (data analysis, written output, etc.)	

Clinical Research Plan

(Go to previous page to submit Non-Clinical Research)

Purpose *Reason for the research*				
Hypothesis				
Patient Population *Defined population and the disease or diagnoses of interest*				
Inclusion *Parameters required to be included in research*				
Exclusion *Parameters that would exclude from research*				
IRB/EC review required				
Number of Subjects		**Number of Sites**		
Samples Size Rationale *Provide statistical rationale*				
Study Visit Schedule	Describe each follow-up visit required			
	Is the visit schedule Standard of Care?	Yes ◯	No ◯, visits outside SOC are:	
Primary Endpoint *Describe clinical assessments, subject reported outcomes, image review, or other data proposed for collection.*				

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Secondary Outcome Measures *Describe clinical assessments, subject reported outcomes, image review, or other data proposed for collection*		
Statistical Analysis *Specify how each outcome measure listed above will be analyzed*		
Clinical Significance or Application		
Background / Summary of publication history on treatment of interest		
Duration of Study	Estimated Start Date of Enrollment	
	Anticipated Duration of Enrollment (in months)	
	Estimated End Date of Follow up Visit Schedule	
	Estimated date of final deliverable (data analysis, written output, etc.)	

Resources Requested

Attach a copy of the budgetary breakdown that clearly shows how the funds requested will be utilized and allocated. Request template if needed.

Funding Requested	Description:	Acumed to provide:	
	Protocol Development	Yes ◯ No ◯	$
	Data Management	Yes ◯ No ◯	$
	Study/Site Oversight	Yes ◯ No ◯	$
	Imaging	Yes ◯ No ◯	$
	Lab	Yes ◯ No ◯	$
	Specimens	Yes ◯ No ◯	$
	Reporting	Yes ◯ No ◯	$
	Biostatistics	Yes ◯ No ◯	$
	Regulatory Submissions	Yes ◯ No ◯	$
	Other:	Yes ◯ No ◯	$
	Other:	Yes ◯ No ◯	$
List Acumed Products Requested			$
Total Funding Requested			**$**
Are there **Other Agreements** in place between the Investigator or Institution and Acumed?			Yes ◯ No ◯

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Output Plans

Mark the **intended output** and **level of evidence** of this research proposal.			
Manuscript for journal publication	☐	Intended journal:	
Abstract to Scientific Meeting	☐	Intended meeting:	
White Paper	☐		
Data only	☐		
Other	☐		
Level of Evidence	Level I	◯	Systemic Reviews; high-quality randomized trials; or prospective study
	Level II	◯	Lesser quality RCT; Prospective comparative study
	Level III	◯	Case control study; Retrospective comparative study; Biomechanical study
	Level IV	◯	Case series; Analyses with no sensitivity analyses
	Level V	◯	Expert opinion.

Attachments

Protocol / Study Plan	☐	
Budget Proposal	☐	
Lead Investigator CV	☐	
Subinvestigator CV	☐	
Subinvestigator CV	☐	
Subinvestigator CV	☐	
Other:	☐	

Acumed is under no obligation to approve a proposal or enter into an agreement until a complete review is conducted. Reviews occur monthly. You will be notified directly once the complete research proposal is reviewed by the Acumed Research Review Committee.

Completed by: _____

Signature: _____ *Date:* _____