

Investigative Site Questionnaire

This document will be used to evaluate and qualify you and your institution for participation in Acumed research. Your consideration for research cannot be reviewed until this form is returned complete. This form is valid for 2 years but you may be asked to verify the information for each research proposal for which you are nominated.

Forward this completed form and your CV to Acumed Clinical Research Department, 5885 NW Cornelius Pass Rd, Hillsboro, Oregon 97124 or email to clinicalresearch@acumed.net.

Investigator	Name			
	Title			
	Address			
	Direct phone		Email	
	States you hold active medical licensure			

Facility/Institution	Name			
	Address			
	Phone		Fax	

Clinical Institution

Institutional diversity of patient population	Race	Hispanic or Latino	____ %			
		Not Hispanic or Latino	____ %			
	Ethnicity	American Indian or Alaskan Native		____ %		
		Asian		____ %		
		Black or African American		____ %		
		Native Hawaiian or Other Pacific Islander		____ %		
		White		____ %		
	Age	12 – 21 years	____ %	50 – 59 years	____ %	
		22 – 29 years	____ %	60 – 69 years	____ %	
		30 – 39 years	____ %	70 – 79 years	____ %	
		40 – 49 years	____ %	80 years and older	____ %	
	Does your facility have a dedicated research facility?				Yes <input type="checkbox"/>	No <input type="checkbox"/>
	Does your facility have an imaging facility (x-rays, MRI)?				Yes <input type="checkbox"/>	No <input type="checkbox"/>
Does your facility have adequate storage space for research study files?				Yes <input type="checkbox"/>	No <input type="checkbox"/>	
Format of patient medical records?		Electronic Medical Records <input type="checkbox"/> Paper Charts <input type="checkbox"/>				
Would Monitor have access to records?		Electronic Medical Records <input type="checkbox"/> Paper Charts <input type="checkbox"/> Certified Copy <input type="checkbox"/>				

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Clinical Experience

Description of your clinical practice				
Description of your patient population				
Therapeutic Area	Area		# surgeries performed per year	Product types used Brands not required; this is to determine familiarity
	Elbow	<input type="checkbox"/>		
	Hand & Wrist	<input type="checkbox"/>		
	Foot & Ankle	<input type="checkbox"/>		
	Hip & Pelvis	<input type="checkbox"/>		
	Shoulder	<input type="checkbox"/>		
	Neck & Spine	<input type="checkbox"/>		
Specialties or Interests				

Clinical Research Experience (if no experience, leave blank)

Clinical Research training	ACRP Certified	Yes <input type="checkbox"/> No <input type="checkbox"/>
	CITI Certified	Yes <input type="checkbox"/> No <input type="checkbox"/>
	Good Clinical Practices (GCPs)	Yes <input type="checkbox"/> No <input type="checkbox"/>
	Human subjects research protection	Yes <input type="checkbox"/> No <input type="checkbox"/>
	HIPAA	Yes <input type="checkbox"/> No <input type="checkbox"/>
	Other	
Number of years' experience in clinical research		
Number of FDA-regulated (IDE or PAS) studies conducted		
Number of non-regulated post-market studies conducted		
Number of nonclinical studies conducted		
Number of studies conducted as Lead Investigator		
Number of studies conducted as Subinvestigator		
Describe studies you are currently participating in (therapeutic area, type of study, phase in study, role)		
Have you or your institution been audited by FDA?	Yes <input type="checkbox"/> No <input type="checkbox"/> If yes, what was/were the outcomes?	

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Clinical Research Coordinator / Research Assistant

Clinical Research Coordinator/ Research Assistant	Name			
	Title			
	Direct phone		Email	
Does the Research Coordinator/Assistant work part-time or full time?				Part-time <input type="checkbox"/> Full-time <input type="checkbox"/>
Does the Research Coordinator/Assistant have other responsibilities beyond research?				Yes <input type="checkbox"/> No <input type="checkbox"/>
Clinical Research Coordinator Training	ACRP Certified	Yes <input type="checkbox"/> No <input type="checkbox"/>		
	CITI Certified	Yes <input type="checkbox"/> No <input type="checkbox"/>		
	Good Clinical Practices (GCPs)	Yes <input type="checkbox"/> No <input type="checkbox"/>		
	Human subjects research protection	Yes <input type="checkbox"/> No <input type="checkbox"/>		
	Responsible conduct of research	Yes <input type="checkbox"/> No <input type="checkbox"/>		
	HIPAA	Yes <input type="checkbox"/> No <input type="checkbox"/>		
	Other			

Subinvestigators

Subinvestigators, if known <input type="checkbox"/> Not Applicable	Name			
	Title			
	Direct phone		Email	
	Name			
	Title			
	Direct phone		Email	

IRB

Local IRB <input type="checkbox"/> Not Applicable	Name			
	Address			
	Contact			
	Phone		Email	
	Local IRB Meeting Schedule?			
Central IRB <input type="checkbox"/> Not Applicable	Name			
	Address			
	Contact			
	Phone		Email	
	Central IRB Meeting Schedule?			

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IRB submission format preference?		Electronic Submission <input type="checkbox"/> Digital Format <input type="checkbox"/> Paper <input type="checkbox"/> Other <input type="checkbox"/>
Reporting Requirements	AEs	
	SAEs	
	UADEs	
	Protocol Deviations	

Please answer the following additional questions. An answer of 'Yes' does not automatically exclude you for research.

Do you have any financial or personal relationships within Acumed that could be considered potential conflicts of interest, including employment, consultancies, stock ownership, or other arrangements.	Yes <input type="checkbox"/> No <input type="checkbox"/>
Do you have any current agreements with Acumed, including royalty agreements, product development agreements, honoraria, or other contracting arrangements?	Yes <input type="checkbox"/> No <input type="checkbox"/>
Has any promise or inducement, verbal or written, been made to you for your potential participation relating to preclinical or clinical research projects?	Yes <input type="checkbox"/> No <input type="checkbox"/>
Are you currently excluded, debarred, or otherwise excluded from conducting clinical research or to participate in federal healthcare programs?	Yes <input type="checkbox"/> No <input type="checkbox"/>
Have you ever been convicted of a criminal offense related to the provision of health care items or services?	Yes <input type="checkbox"/> No <input type="checkbox"/>
Is your institution currently excluded, debarred, or otherwise excluded from conducting clinical research or to participate in federal healthcare programs?	Yes <input type="checkbox"/> No <input type="checkbox"/>

Reviews are conducted monthly by the Acumed Research Review Committee. An Acumed representative will communicate with you following any review for which you have been submitted for consideration.

Name: _____

Signature: _____ Date: _____