UAMS
UNIVERSITY OF ARKANSAS FOR MEDICAL SCIENCES

Office of Research Regulatory Affairs
IDE Support Services Form

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Protocol Title	
Principal Investigator	
Contact Person	
Regulatory Affairs	Lyndsey Avery 686-5190; Melisa Clark 686-8098
Monitoring	Amy Jo Jenkins 686-5939; Kim Morehead 686-7976; Pat Savary 686-6092
Quality Assurance	Larry Parker 686-6284

Regulatory Services/Activities and Documents Needed for IDE	ORRA Staff	Investigator
Regulatory Analysis / Risk Determination (by Committee)	Regulatory Affairs Unit to complete and submit to the IRB	PI gets a copy from Regulatory Affairs
Protocol and Informed Consent Development	Project Team Leader Unit can provide a template to develop these documents	PI to develop with input of Project Team Leader Unit as needed
IDE Submission 1. Prepare (Gather appropriate & applicable documents, forms, letter and other required materials for thorough FDA review) 2. Assemble (Format, Review for completeness/consistency, make paper and digital copies) 3. Submit to appropriate FDA Review Division	Regulatory Affairs Unit completes	Reviews for accuracy
Literature: • All published preclinical testing with device • All published clinical testing done with device • Summary of testing that has not been published, if any	Regulatory Affairs Unit obtains from PI	PI to provide Regulatory Affairs
Manufacturing Information: • Description of methods, facilities, and controls used for the manufacture, processing, packaging, storage, and installation	Quality Assurance Unit will complete	PI needs to contact Quality Assurance to complete
Letter of Cross Reference from Device Manufacturer	Regulatory Affairs Unit will obtain from manufacturer	PI to provide Regulatory Affairs Unit with all device information (make, model, etc.)
Investigator Agreements, CV's, and Statements of Relevant Experience	Regulatory Affairs Unit will obtain from all Investigators	Investigators to complete and return to Regulatory Affairs
Sales information: • Will the device be sold by the manufacturer to the PI? If so, what is the amount to be charges? • Will the subject be charged for the device? If so, what is the amount to be charged? • FDA must approve sale of the device to the site • FDA will assign a reimbursement category to the device	Regulatory Affairs Unit will obtain from PI	PI to send information to Regulatory Affairs Unit

Device Labeling: • Any labeling that accompanies the device (immediate packaging, manuals, carton label, labels affixed to the device, installation information, subject information, etc.) • Will submit all labeling, including pictures of the device	Regulatory Affairs Unit will obtain from the PI	PI will give information to Regulatory Affairs Unit
Protocol/Informed Consent documents that have been reviewed and approved by the UAMS IRB	Regulatory Affairs Unit will obtain final documents from ARIA	N/A
IRB Approval Letters	Regulatory Affairs Unit will obtain from ARIA	N/A
Case Reporting Forms • All will be submitted with the application • Must be IRB approved	Monitoring Unit will help PI develop as needed; Regulatory Affairs Unit will obtain documents from Monitoring Unit	PI/study staff to work with Monitoring Unit
Scientific Soundness Review of the Protocol • Performed by the Director of the Research Support Center	Regulatory Affairs Unit will provide the ORRA Director with template to complete	N/A
Risk Analysis • Description of all increased risks to the subject and how these risk shall be minimized (can come from the PI or protocol)	Regulatory Affairs Unit will obtain from PI or protocol	PI will complete, if necessary
Study Monitoring • Study Initiation Visit • Periodic site monitoring visits • Monitoring Plan (submitted with IDE) • Close out visit	Monitoring Unit will provide	N/A
Maintain IDE • Manage all FDA correspondence (including formal/informal responses, teleconferences, etc.) • Manage official IDE Sponsor file (will be maintained in ORRA file room) • Make all FDA submissions and submit copies as necessary		
IDE Amendments / Supplements • If changes occur during 30 day review, submitted as IDE amendment • Determine if supplements should be prior approved by FDA, changes effected with notice FDA within 5 days, changes submitted in annual report		
Unanticipated Adverse Device Effects (UADEs) • Sponsor to make a determination as to whether the event meets the definition and needs to be submitted to FDA	Regulatory Affairs Unit will submit report to FDA	PI/staff to notify Regulatory Affairs immediately
Reports • Progress (annual and final), Current Investigator List	Regulatory Affairs Unit will submit to FDA	PI/study staff to prepare