UAMS
UNIVERSITY OF ARKANSAS FOR MEDICAL SCIENCES

Office of Research Regulatory Affairs
Regulatory Affairs
IND Support Services Form

Main Phone: 501-526-6876
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Protocol Title/IRB #	
Principal Investigator	
Contact Person	
IND/FDA Submissions	Carole Hamon 526-7437; 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 Affairs Services	ORRA Staff	Investigator/Staff
Perform Regulatory Analysis Analyze Protocol/Informed Consent in conjunction with Package Insert/Investigator's Brochure for FDA involvement.	ORRA completes & submits to PI	PI uploads to IRB File
Obtain Final Protocol and Informed Consent	ORRA files with IND	PI sends to ORRA
IND or IND Exemption Submission 1. IND a. Prepare (Gather appropriate & applicable documents, forms, letters and other required materials for thorough FDA review) b. Assemble (Format, Review for completeness/consistency, make paper and digital copies) c. Submit to appropriate FDA Review Division	ORRA completes	Reviews for accuracy as needed
Transmittal/Cover Letter Preparation	ORRA completes & (VCR) signs	
1571 Form 1. Prepare 2. Obtain Vice Chancellor for Research (VCR) Signature 3. Verify Sub-Investigators and Medical Monitor	ORRA prepares	
1572 Form 1. Prepare; verify Sub-Investigators 2. Verify Laboratories – CLIA/CAP 3. Obtain Signature(s)	ORRA prepares	Review & Sign
Obtain CV and Medical License Copy 1. PI 2. Co-Investigators 3. Medical Monitor	ORRA files/holds	PI sends to ORRA
Obtain Package Insert(s) or Investigator's Brochure	ORRA obtains in concert with PI	PI uploads to study IRB File
Chemistry, Manufacturing and Controls Section & Investigational Drug Product Labeling	ORRA QA in concert with pharmacist	PI input as required

Regulatory Affairs Services	ORRA Staff	Investigator
Pharmacology and Toxicology/Non-Clinical Data	ORRA files with IND	PI supplies All animal work (GLP or not), lab bench work, & any information – published or otherwise to ORRA
Previous Human Experience/Clinical Data	ORRA files with IND	PI supplies any information – published or otherwise to ORRA
Any Additional Information	ORRA files with IND (if applicable)	PI supplies any additional information
Case Reporting Forms Preparation	ORRA works with PI	PI reviews and approves forms
Monitoring of ongoing study	ORRA	PI and/or staff supply information as requested
Maintain IND 1. Manage FDA Correspondence (IND Status/Activation & official responses.) 2. Create IND Binder (Official IND Sponsor Historical File) 3. Distribute copies as appropriate	ORRA	PI and/or staff supply information as requested
IND Amendments 1. Protocol (in conjunction with PI and/or Staff) a. Prepare Comparison Document b. Check for IRB approval for appropriate statement c. File amendment 2. Informed Consent (in conjunction with PI and/or Staff) a. Prepare Comparison Document b. Check for IRB approval for appropriate statement c. File amendment 3. CMC Updates – stability data, change in manufacturing process, reports promised to FDA (in conjunction with PI and/or Staff) 4. Distribute copies of IND Amendment Submissions	ORRA files to active IND at post IRB approval	PI informs ORRA of all protocol and/or informed consent changes and sends final, approved documents to ORRA for IND submission.
IND Annual Reports	ORRA notifies PI 2 months & 2 weeks from annual report due date, & at due date. Reviews, & submits to FDA	PI prepares annual report per ORRA template
SAE Submissions 1. Prepare 2. Submit	ORRA reviews & files to IND	PI sends documents to ORRA
Clinical Holds/FDA Comments/FDA Questions 1. Prepares/oversee reply 2. Submit	ORRA immediately informs PI, reviews, formats, & submits PI response to FDA	PI prepares response to Clinical Holds/FDA Comments/FDA Questions
FDA Teleconferences 1. Arrange/coordinate 2. Conduct 3. Minutes preparation and distribution	ORRA coordinates	PI & others attend