Preparation Packet for Investigator-Initiated Drug and Device Studies

The following is an overview of the steps that investigators need to follow when preparing an investigator-initiated drug or device study. This information is intended to prepare investigators for meeting the requirements of the FDA and IRB. This information is for guidance only and should not be viewed as a comprehensive list of requirements. It is the responsibility of each investigator to ensure that all requirements for the FDA and IRB are met.

Please contact the IRB (801.581.3655) if you have any questions regarding this guidance.

Step 1: Write the study protocol.

Clinical research protocol templates are widely available on the internet. The IRB does not endorse a particular template or format. E6(R2) Good Clinical Practice: Integrated Addendum outlines the necessary information for a clinical trial protocol and protocol amendments in section 6. It is highly suggested that this section be used to draft a study protocol, to ensure that all components of the protocol are described.

Step 2: Determine if an IND/IDE is needed.

	Investigational Drugs - IND	Investigational Devices - IDE
FDA Regulations	21 CFR 312	21 CFR 812
Guidance	Investigational New Drug Applications (INDs) - Determining Whether Human Research Studies Can Be Conducted Without an IND (FDA Guidance) Index: Investigational Drugs & Biologics (UU Guidance)	Significant Risk and Nonsignificant Risk Medical Device Studies (FDA Information Sheet; Includes examples of SR and NSR devices) Index: Investigational Devices (UU Guidance)

Initial FDA Paperwork for Applications	1. IND Application: Instructions in 21 CFR 312.22-23
	    1. Information for Sponsor-Investigators Submitting Investigational New Drug Applications (INDs) (FDA Guidance)
	2. FDA Form 1571 (IND Application Cover Form): Form (PDF) | Instructions
	3. FDA Form 1572, Statement from Investigator: Form (PDF) | FAQ - Statement of Investigator (FDA Guidance)
	4. FDA Form 3674, Certificate of Compliance: Form (PDF)
	    1. Register the study on ClinicalTrials.gov.
	5. If applicable, a written request for charging the cost of the investigational drug to subjects
	6. Conflicts of interest (financial disclosures) for all participating investigators
	    1. Financial Disclosure by Clinical Investigators (FDA Guidance)
	
	The FDA paperwork is not required to be submitted to the IRB. After submission, the FDA will respond within 30 days. All documentation received from the FDA must be kept on file and submitted to the IRB, including the IND approval/confirmation letter and, if
		1. IDE Application: Instructions in 21 CFR 812.20
		    1. IDE Approval Process (FDA Guidance)
		2. FDA Form 3674, Certificate of Compliance: Form (PDF)
		    1. Register the study on ClinicalTrials.gov.
		3. Conflicts of interest (financial disclosures) for all participating investigators
		    1. Financial Disclosure by Clinical Investigators (FDA Guidance)
		
		Sponsor-Investigators are encouraged to contact the FDA to obtain further guidance prior to the submission of an IDE application through the Pre-IDE Submission Process.
		
		The FDA paperwork is not required to be submitted to the IRB. After submission, the FDA will respond within 30 days. All documentation received from the FDA must be kept on file and submitted to the IRB, including the IDE approval/confirmation letter.

	applicable, the FDA letter approving investigational agent charges to subjects.	

Step 3: Create study policies and procedures.

Sponsor-Investigator Policies and Procedures Templates	• Drug / Biologics [DOC] • Devices

Guidance related to Sponsor-Investigator Responsibilities	• IRB guidance on sponsor-investigator responsibilities [PDF]
	• Investigator Responsibilities:
	  ◦ Drug / Biologic studies [PDF]
	  ◦ Device studies [PDF]
	• Data safety and monitoring plans:
	  ◦ IRB guidance

Step 4: Complete all items on the IND/IDE checklist.

The IRB requires that the study receive an assessment *before* IRB approval of the new study application is granted. This assessment is to ensure that all documentation is in place before the study begins, increasing the study team's ability to maintain compliance with FDA regulation. Please contact the University of Utah Clinical Research Support Office Quality Assurance Group (CRSOQA@hsc.utah.edu) to schedule the pre-IND or pre-IDE assessment.

At the conclusion of the audit, any changes required by the auditor should be made the the IRB application and the audit report should also be attached to the IRB application (under "Other Documents" on the Documents and Attachments page).

Step 5: Obtain IRB approval.

The new study application must be submitted for review. The application must indicate that the study represents an investigator-initiated drug or device trial (HIPAA & the Covered Entity page, question c) and all relevant drug/device pages must be completed. Investigators may choose to submit the IRB application before the IND/IDE approval/confirmation has been

received from the FDA or before the Pre-IND/IDE audit has been completed; however, you must include a statement in IRB application that this is pending.

Step 6: Conduct ongoing reporting and monitoring of the study, according to the policies and procedures.

After a study receives IRB approval, Sponsor-Investigators are responsible for ensuring that all FDA regulations are followed by using the study policies and procedures. The University of Utah Clinical Research Support Office Quality Assurance team may perform ongoing audits to ensure compliance.