P.I. Has Preliminary Discussions with Sponsor

Confidentiality Agreement
ECU Pre-Approved Agreement vs. Submit Sponsor Agreement to OSP
Signed by P.I. & Sent to OSP for Review, Negotiation & Signature

P. I. Receives Protocol & Determines Feasibility
Use Pre-Study Checklist as a Guide

P. I. Contacts Other Departments to Determine Specific Costs
Laboratory Tests, X-rays, IRB, Pharmacy, etc.

Prepare Preliminary/Internal Budget
Fill Out Forms Listed Below

Make Submission for Approval to Clinical Trials Working Group
Clinical Trial Salary Worksheet and Clinical Trial Test & Assessment Cost Worksheet
Protocol

After Internal Budget Approved, P. I. Negotiates Budget with Sponsor that at least covers these anticipated costs

Administration and Finance Submission
Internal Processing Form
Multi-Disciplinary Project Form
Draft Contract with Sponsor Budget
Abstract of Application
Project Classification Form
Final Clinical Trial Salary Worksheet and Clinical Trial Test & Assessment Cost Worksheet
Contact Sheet

UMCIRB Submission
With Institutional Approval Committee Signatures

Establish Account in Grant and Contracts Administration

Start Clinical Trial

Preliminary Compliance Review
Triggered by receipt of first patient payment and corresponding Time & Effort Report