CLINICAL TRIAL APPROVAL PROCESS

Research Intake Application (RIA)
After submission, study submission will undergo a completeness check before UAHS & Medical Partner conduct a feasibility assessment and approval for project to proceed.

ESSENTIAL DOCUMENTS:

- IRB Forms*
- Contract Draft*
- Protocol*
- Consent Draft*
- Budget Draft
- Schedule of Events from Protocol*

(needed for development of CA)

Medical Partner

IRB Review

- Finalized budget and payment terms included into contract

Contract routed for signatures by all parties

IRB Approves

Contract Fully Executed*

Med. Partner Approves?

Yes?

No? Revise CA

UAHS Research Administration

Develop Coverage Analysis (CA)

Sponsor Negotiation

Sponsor Approves?

Yes?

No?

Budget Approved*

1. UAHS Completes PDD/UAR
2. Finalized budget & payment terms are added to contract prior to finalization.

Coverage Analysis Review Memo (CARM) sent to PI for review & signature

STUDY TEAM must email the final IRB approved Informed Consent Form(s) to UAHS Research Administration at crc@email.arizona.edu

FINAL STEP: Upon completion of all study start up activities, UAHS RA will email a final document packet to Study Team & medical partner of all approval documents (CTA/Budget, CA) or upload to the Clinical Trial Management System (CTMS)