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*

Assigned to UAHS Contract Negotiator for initial redlines

Medical Partner

Sponsor

iRB Review

Finalized budget and payment terms included into contract

Contract routed for signatures by all parties

IRB Approves

Contract Fully Executed*

UAHS Budget Development
UAHS Research Administration collaborates with Study Team

Sponsor Negotiation

CA Approved*

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

Yes?

Med. Partner Approves?

Yes?

Sponsor Approves?

No?

Budget Approved*

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

**indicates documents that are sent to medical partner by UAHS
*IRB Forms include: Application for Human Research, List of Research Personnel, PI CV, data collection tools, recruitment materials, etc.

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)