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*

** 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.

CONTRACT DEVELOPMENT:

- Assigned to UAHS Contract Negotiator for initial redlines
- Contract routed for signatures by all parties
- IRB Review

DEVELOPMENT OF BUDGET:

- Finalized budget and payment terms included into contract
- Sponsored Negotiation
- Sponsor Approves?
- Yes?
- No?

FINANCIAL APPROVAL:

- UAHS Budget Development
- UAHS Research Administration collaborates with Study Team
- CA Approved*
- Coverage Analysis Review Memo (CARM) sent to PI for review & signature
- Sponsor Approves?
- Yes?
- No?
- Budget Approved*
- 1. UAHS Completes PDD/UIAR
- 2. Finalized budget & payment terms are added to contract prior to finalization.

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).