Conduct internal feasibility review. This includes review of protocol, data collection instruments, determination if Banner resources will be utilized, review of draft contract/budget for COMP specific items.

Submit to CReSS Regulatory Team

Draft documents for Banner Feasibility and IRB Review:
- IRB Application
- IRB appendices
- Informed Consent Form (for prospective studies)
- RIA Form

Submit to Banner for Feasibility Review

Banner Feasibility Review and Approval
- Determination if an agreement is needed if data is being shared with individuals outside of Banner/UA.
- If clarifications requested, CReSS Clinical Research manager will work with Banner and study team to resolve.

Documents routed to UAHS for the following:
- Development of Payor Coverage analysis (1 week)
- Study shell built in Oncore (1 week)
- Review/negotiate budget (if necessary)
- Negotiation and execution of study agreements i.e. DUA, sub-award, CTA, etc.

Externally Funded Only:
Sponsored Projects to provide Institutional Proposal Number prior to submitting to IRB

Complete COI Disclosure

Finalize and submit documents to UA IRB
(Timeline: 2 weeks)

If applicable, register study on https://clinicaltrials.gov/ (Timeline: 2-4 weeks)

IRB approved documents uploaded to Oncore. Study team notified they may proceed with site initiation and begin enrollment. (Timeline: 1 week)

For Industry Sponsored Clinical Trials, study team:
- Completes feasibility questionnaire
- Conducts pre-study visit with Sponsor

(Timeline: 2 weeks)

(Timeline: 30 days)

Route CDA to Investigator for signature

Sign CDA and route back to UAHS for Institutional signatures

Sponsor uploads all submits all study documents (regulatory, contract/budget) to Pre-Fas CReSS- Sponsored Study Start up system

(Timeline: 1-2 weeks)

(Timeline: 2 weeks)

If applicable, register study on https://clinicaltrials.gov/ (Timeline: 2-4 weeks)

IRB approved documents uploaded to Oncore. Study team notified they may proceed with site initiation and begin enrollment. (Timeline: 1 week)

Clinical Research Support Services (CReSS) Contacts:
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Legend
- Investigator
- CReSS Clinical Research Manager
- CReSS Regulatory Team
- Banner Research
- UAHS

Sponsored Study – COMP Study Start-up Process Flow

After submit to CReSS Regulatory Team, ideal timeline to active IRB and study start is 3-6 months for Industry Sponsored Studies.