Investigator Initiated Study – COMP Study Start-up Process Flow

Legend
- Investigator
- CReSS Clinical Research Manager
- CReSS Regulatory Team
- Banner Research
- UAHS

For RETROspective Studies:
- Draft study protocol
- Ensure current literature review completed, if resident/medical student
- Compile list of data elements to be collected
  - Where will data be stored? REDCap (recommended), UA Box Health, Other, specify.
- Identify study team members. Include individuals directly involved with data collection
- Obtain signed/dated copy of Principal Investigator CV or Biosketch
- ***Click on this CReSS link for study protocol template with key weblinks***

CReSS-retrospective protocol-template 2

For PROspective Studies:
- Draft study protocol
- Draft Schedule of Events table
- Compile list of data elements and/or data collection tools to be collected/used
  - Where will data be stored? REDCap (recommended), UA Box Health, Other, specify.
- Identify study team members who will be directly involved with data collection or completing study procedures
- Obtain signed/dated copy of Principal Investigator CV or Biosketch
- ***Click on this CReSS link for study protocol template with key weblinks***

CReSS-prospective protocol-template 2

Submit to CReSS Clinical Research Manager and/or Director.

Submit to Investigator Initiated Study intake portal (Pre-Fas)

Conduct internal feasibility review. This includes review of protocol, data collection instruments, determination if Banner resources will be utilized, and if funding support is needed.

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

(Timeline: 2 weeks)

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.

(Timeline: 1-2 weeks)

Documents routed to UAHS for the following (for prospective studies):
- 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.

(Timeline for budget/contract execution: 90 days)

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

(Timeline: 2-3 weeks)

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 begin enrollment.

(Timeline: 1 week)

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After submit to CReSS Regulatory Team, ideal timeline to active IRB and study start is 1-3 months for RETROspective Studies and 3-6 months for PROspective Studies.