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](https://cressprotocoltemplate2)

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](https://cressprotocoltemplate2)

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

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)

External 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/](https://clinicaltrials.gov/) (Timeline: 2-4 weeks)

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

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)

Clinical Research Support Services (CReSS) Contacts:
Anna Valencia, Senior Director Clinical Research Operations – atvalencia@arizona.edu
Stephanie Marsh, Director, Clinical Research Operations – slmarsh@arizona.edu

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

For RETROSpective Studies:
- Draft study protocol
- IRB Review:
  - IRB Application
  - IRB appendices
  - Informed Consent Form (for prospective studies)
  - RIA Form
  (Timeline: 2 weeks)

Submit to CReSS Clinical Research Manager and/or Director.

For PROSpective Studies:
- Draft study protocol
- IRB Application
- IRB appendices
- Informed Consent Form (for prospective studies)
- RIA Form
- [Timeline: 2 weeks]