School of Medicine

Clinical Research Startup Process

At VCU, the School of Medicine (SOM) has a specific clinical research startup process that we follow to activate studies. Once our site has been selected, we will need the regulatory packet. The study team will send you a feasibility to complete and return to us prior to initiating our internal activation process. To activate the startup process, we need the following documents (**at a minimum**):

1. Feasibility
2. Protocol
3. CTA Template
4. Budget Template
5. ICF Template
6. Investigator's Brochure

Once we receive the items listed above, we submit to our internal Protocol Review and Oversight Committee (PROC) for approval to proceed. The PROC has a 1–2-week turnaround time for most submissions. Once PROC approval is obtained, the study team completes an internal intake form for VCU Health Services/Pricing, creation of the study in EPIC, and initiation of the School of Medicine Clinical Research Office (SOMCRO) intake process. Upon SOMCRO intake, study documents are distributed to the different teams involved in startup.

The following teams are all simultaneously involved in the startup process:

Regulatory Documents / IRB Submissions / Project Oversight – Study team
ICF injury language and Contracts - Division of Sponsored Programs (DSP)
Coverage Analysis and Budget Negotiations- Budgets Team (SOMCRO)
Pricing quotes and EPIC Build – VCU Health Office of Clinical Research

**The pharmacy, pathology, and/or imaging manuals are required for pricing quotes from VCU Health*

You will likely hear from DSP first to negotiate the injury language in the ICF. The regulatory documents will be provided by the Regulatory or Clinical Research Coordinator shortly thereafter, usually within a month of startup initiation. Once the injury language is agreed upon, the study team submits to our local VCU RAMS IRB. VCU RAMS IRB will do a review and cede overall management to the Central IRB. Our IRB meets bi-weekly and in general, this takes 1-2 months. We will then submit everything to the CIRB. This process is done in parallel with all negotiations and we only need the agreed injury language to proceed with local IRB submission. The same team (DSP) who contacted you for the injury language discussion, will proceed with contract negotiations. For the contract to be fully executed, the budget must be complete and IRB approval must be obtained.

A Budget Project Manager will contact you for budget negotiations. The project manager will complete a Coverage Analysis assessment and meet with the study team to discuss activation and time requirements. When these activities are complete, they will begin to work on a budget draft. Once they receive the internal quotes from VCU Health, they will utilize your budget template to send to you for negotiations.

The overall time frame from document receipt to contract completion varies. Average activation times are 16-24 weeks for Industry Clinical Trials in The School of Medicine at VCU, although we are working to improve our activation timelines daily! We do try to execute all agreements as soon as possible.