



INFORMATION FOR SPONSORS/CROs

Regarding Mayo Clinic's Accelerated Clinical Trial Activation Process

Mayo Clinic works directly with Sponsors/CROs to expedite study activation for clinical trials. We will work closely with you in order to achieve study activation in an efficient manner while maintaining the highest level of accuracy.



At Mayo Clinic, four phases of activities are completed to prepare a new industry-sponsored study through activation to open to enrollment. **Each phase must be completed in its entirety before the subsequent phase can begin.**

Sponsor Document Collection (Timeline Goal: [Dependent upon availability of Sponsor documents](#))

- The first step is to collect critical information required to initiate the study assessment and start-up processes.
- Specifically, if applicable to your trial, the documents required are:
 - Final protocol
 - Informed Consent (draft)
 - Budget template (draft)
 - Clinical Trial Agreement (draft)
 - Investigator Brochure
 - Device Manual
 - Lab Manual
 - Recombinant DNA Advisory Committee Letter
 - Pathology Manual
 - Pharmacy Manual
 - Imaging Manual
 - FDA letter (IND/IDE designation) or justification
 - Participant contact materials
 - Advertising materials
 - Completed Company Information Sheet (provided by Mayo)
- The information in these documents is **required** to start the study assessment process at Mayo Clinic. Study teams are instructed to await the receipt of all applicable documents prior to initiating study assessment activities (internal or departmental approvals, budget requests, scientific review, etc.).
- **Your timely attention to submitting documents is critical**

Study Assessment (Timeline Goal: Approximately 4-6 weeks, contingent upon departmental prioritization)

Once all documents are received, the study is assigned to a study team in the investigator's department.

- The study assessment process begins after receipt of all required documents and typically requires four to six weeks to complete. Timelines **may** be affected by committee review schedules and Sponsor review and approval responsiveness.
- Required assessment activities may include but are not limited to:
 - Disease Group approval (Depending on the department; may occur earlier in some departments)
 - Scientific or Departmental Committee Reviews (Some departments may require a separate prioritization assessment)
 - Accrual feasibility assessment
 - Gathering necessary budget elements including personnel efforts, apheresis, pharmacy, radiology, laboratory, and any other required service costs
 - Converting the informed consent document to the Mayo template and obtaining your initial approval
 - Completion of IRBe Financial Disclosures for study
 - Preparation of the IRB application
 - Third Party Risk Management (TPRM), if applicable
 - Assessment of equipment needs
 - Any ancillary committee approvals that may be required prior to the study start-up submission (IBC, Pediatrics, OB/GYN, etc.)
- Please note, some committees do not meet as frequently

Study Start-Up (Timeline Goal: ≤65 days, pending study design and your commitment to timelines)

At Mayo Clinic, study start-up refers to budget review and negotiation, contract negotiation, additional ancillary committee approval and IRB submission and approval, which are completed in parallel.

Study assessment must be complete in order to submit the study to the institutional shared services for the study start-up process.

- The Office of Clinical Trials will contact you near the completion of the study assessment process to schedule a teleconference and discuss the shared services activation timeline.
- We will review the activation process and request your commitment to the shared services activation timeline which includes negotiating the budget and contract and IRB approval.

Study Set-up Activities (Timeline Goal: Varies by Sponsor guideline requirements and departmental prioritization)

These activities may include:

- Lab/Pharmacy/Service Area Set-up
- Regulatory files
- Staff study training and delegation
- Equipment/device procurement, if applicable
- Epic builds, if applicable
- Site Initiation Visit
- Upon completion of these activities, the study will be opened to enrollment

If you have any questions regarding the process to develop and activate a study at Mayo Clinic, please contact the Office of Clinical Trials at OfficeofClinicalTrials@mayo.edu or (507) 284-5580.

We look forward to working with you.