

## 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, we have four phases of activities to prepare a new industry-sponsored study. **Each phase must be completed in its entirety before the subsequent phase can begin.**



### Sponsor Document Collection (Timeline Goal: Dependent on availability of Sponsor documents)

- The first step in this process is to collect critical information needed to begin the study development and activation processes.
- Specifically, if applicable to your trial, the documents we require are:
 

<ul style="list-style-type: none"> <li>▪ Final protocol</li> <li>▪ Informed Consent (draft)</li> <li>▪ Budget template (draft)</li> <li>▪ Clinical Trial Agreement (draft)</li> <li>▪ Investigator Brochure</li> <li>▪ Device Manual</li> <li>▪ DSMB Charter (at a minimum, must have a draft) or justification</li> <li>▪ Lab Manual</li> <li>▪ Recombinant DNA Advisory Committee Letter</li> </ul>	<ul style="list-style-type: none"> <li>▪ Pathology Manual</li> <li>▪ Pharmacy Manual</li> <li>▪ Imaging Manual</li> <li>▪ FDA letter (IND/IDE designation) or justification</li> <li>▪ Participant contact materials</li> <li>▪ Advertising materials</li> <li>▪ Clinicaltrials.gov # (or justification)</li> <li>▪ Completed Company Information Sheet (provided by Mayo)</li> </ul>
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- The information in these documents is **required** to begin study development at Mayo Clinic. Our study teams are instructed to wait for the receipt of all applicable documents before initiating study development activities (internal or departmental approvals, budget requests, scientific review, etc.).
- **Your timely attention to the initial request for documents is critical to the study development process.**



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

Once all study documents are received, your study will be assigned to a study development team in your investigator's department.

- The study development process will typically require approximately four to six weeks after all Sponsor documents are provided but **may** be affected by committee review schedules and Sponsor responsiveness for reviews and approvals.
- Development activities that need to be completed include but are not limited to:
  - Disease Oriented 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
  - Drafting the informed consent document onto the Mayo template and obtaining your initial approval
  - Completion of IRBe Financial Disclosures for all study teams
  - Preparation of the IRB application
  - Security, Privacy, Architecture, & Data (SPAD) Assurances approval, if applicable
  - Assessment of equipment needs
  - Any ancillary committee approvals that may be required prior to the business unit activation segment (IBC, Pediatrics, OB/GYN, Security Privacy Architecture & Data Assurance etc.)
    - Please note, some committees do not meet as frequently

**Business Unit Activation Process (Timeline Goal: ≤65 days, pending study design and your commitment to timelines)**

- At Mayo Clinic, Clinical Trial Business Unit Activation refers to budget creation and negotiation, contract negotiation, additional ancillary committee approval and IRB submission and approval, which are completed in parallel.
- Once study development is complete, we can officially engage in the institutional business unit activation process.
- The Office of Clinical Trials will contact you near the completion of the Study Development process to schedule a Sponsor call and share the business unit activation timeline.
- We will discuss the activation process and obtain your commitment to meeting the anticipated deadlines for negotiating budget and contract as well as obtaining IRB approval from Mayo.



**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

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](mailto:OfficeofClinicalTrials@mayo.edu) or (507) 284-5580.

We look forward to working with you.