Information for Sponsors/CROs regarding Mayo Clinic’s Accelerated 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 reach the shared goal of achieving study activation in an efficient manner while maintaining the highest level of accuracy.

At Mayo Clinic, we have three phases of activities to prepare a new industry-sponsored study:

**Sponsor Document Collection**

- The first step in this process is to collect information from you that is critical to Mayo Clinic during the study development and activation processes.
- Specifically, if applicable to your trial, the documents we require are:
  - Final protocol
  - Informed Consent (draft)
  - Budget template (draft)
  - Clinical Trial Agreement (draft)
  - Investigator Brochure
  - Device Manual
  - DSMB Charter (at a minimum, must have a draft)
  - Lab Manual
  - Recombinant DNA Advisory Committee Letter
  - Pathology Manual
  - Pharmacy Manual
  - Imaging Manual
  - FDA letter (IND/IDE designation)
  - Participant contact materials
  - Advertising materials
  - Clinicaltrials.gov #
  - Completion of the provided Company Information Sheet

- The information in these documents is required for study development within Mayo Clinic. Our study staff are instructed to wait for the receipt of all applicable documents before moving forward with initiating the IRB application, budget, and contract processes.
- Since the study development process will not begin until we have received these documents, your timely attention is appreciated.
Study Development (timeline goal: ~4-6 weeks)

- Once all study documents are received, your study will be assigned to a study development team in your investigator’s department. They have several development activities to complete in order for your study to be ready to enter the activation process, including:
  - Disease Oriented Group approval (depending on the department; may occur earlier in some departments)
  - Scientific or Departmental Committee Reviews
  - Some departments require a separate prioritization assessment
  - Accrual feasibility assessment
  - Gathering budget elements including personnel efforts, pharmacy, radiology, laboratory, and any other required service costs
  - Drafting the informed consent document on our Mayo template and obtaining your approval
  - IRBe Financial Disclosures for all study staff
  - Preparation of the IRB application
- The study development process will typically require one month after all Sponsor documents are available but may be affected by committee review schedules and Sponsor responsiveness for reviews and approvals.

Activation Process (timeline goal: ≤65 days, pending project type and your commitment to timelines)

- Budget creation and negotiation, contract negotiation, and IRB committee reviews are completed in parallel
- The Office of Clinical Trials will contact you during the Study Development process once we have developed the activation timeline. We will provide you with anticipated dates for receipt of budget, contract redlines, and IRB approval from Mayo. In our accelerated process, we aim to complete these three activities in parallel with your commitment to this accelerated review schedule.

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.