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Streamlining the Study Feasibility Review Process at an Academic Medical Center

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Industry sponsors favor research sites that start clinical studies quickly. Academic medical centers (AMCs) have been at a disadvantage because of their complex organizations and processes. Starting a clinical trial can require review and approval by numerous committees and people with authority over various functions. For example, at Northeast Georgia Medical Center (NGMC), the following committees must approve new studies:

- Research Executive Committee
- Research Operations Committee
- Medical Department/Specialty Research Committees

The following individuals must also approve new studies:

- Chief Medical Officer
- Director, Research Administration
- Directors, Medical Department/Specialty
- Federalwide Assurance (FWA) signatory official
- Revenue cycle representative
- Finance representative
- Compliance representative
- Public relations representative
- Clinical service line (group of departments) representative
- Information technology representatives
- Affiliated site representatives
- Patient registration representative
- Scheduling representative

As a result, until recently, NGMC study startup times averaged six months. Over the past two years, we have refined our operational processes to reduce startup times to three months on average and much faster for priority projects, while also reducing cost and maintaining or improving rigor.

We have taken the following steps to accomplish this goal:

1. Set Clear Goal

We set the following goal:

> Over a 12-month period, reduce the average time to clinical study activation from six months to three months by revising the review process and standardizing on a

consolidated feasibility assessment tool. Startup time is measured as the number of days from date of protocol receipt to the date when a study can start enrolling participants.

2. Establish leadership

The Research Executive Committee sets goals and strategy for the research program at the institutional level. Membership includes the chief medical officer (chairperson), the director of research administration, the VP, medical education and principal investigator representatives. The Research Executive Committee meets quarterly to review results and set goals for the research program going forward.

3. Engage key stakeholders

Accomplishing our goal required cooperation across the organization. The director of research administration or a designee served as project leader, coordinating efforts and facilitating operational processes and communications. The project team included a key stakeholder and point of contact from each relevant area.

We also obtained documented support from institutional leadership and created standardized messaging.

4. Collect standard information for feasibility review

A single, standardized feasibility assessment tool (Appendix 1) supports all review activities. The Office of Research Administration maintains the document, with a project manager collecting information in parallel from relevant personnel.

5. Consolidate reviews

All institution-level reviewers have been consolidated into the Research Operations Committee, which is chaired by the director of research administration and includes representatives from the list at the top of this article. It meets monthly to review feasibility assessments submitted by the departmental/specialty research committees.

All reviewers at the department level in each department/specialty have been consolidated into a Clinical Department/Specialty Research Committee. Depending on study volume, these committees meet monthly or every other month. Each of these committees is chaired by a departmental/specialty leader and includes three to 20 members, including principal investigators, sub-investigators and other research and administrative staff.

Materials for expedited reviews are distributed and voted on by email.

Any committee members who miss a meeting receive the materials and vote on approval by email.

6. Standardize review processes

All research committees have charters, bylaws, training programs and established schedules. Members receive the standardized feasibility assessment tool and other relevant materials for each study one to two weeks before meetings.

7. Coordinate review processes with administrative functions.

A study startup process is much faster when component processes are conducted in parallel rather than sequentially.[1,2] Although parallel processes might lead to wasted effort, research sites that want to be competitive on startup timelines have no other option.

Once the director of research administration approves a study for entry into the feasibility process, other processes (e.g., legal and financial reviews) can proceed in parallel. When a necessary resource (e.g., equipment) is identified during the feasibility process, the project leader submits a request for the resource with an estimated timeframe. If no concerns are anticipated at the Department/Specialty and Research Operations Committee meetings and the legal team has performed at least a first-pass review of the study contract, the study can be submitted for IRB review.

Appendix 2 lays out the Clinical Research Study Startup Process in Appendix 2 lays out the workflow process.

8. Leverage the use of appropriate technology

The review process is facilitated by technology, including a clinical trial management system (CTMS), eRegulatory, project management, shared document authoring and virtual meeting platforms.

9. Pilot the system in one department

We piloted the proposed, streamlined workflow in one department for about three months before implementing it across the institution for all studies.

Conclusion

By creating a standardized, comprehensive study feasibility form, consolidating the key stakeholders who approve studies into a few committees and conducting startup activities in parallel, a complex AMC reduced average study activation time from six to three months, along with improving review quality and rigor and optimizing the use of personnel time.

References

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2. Goldfarb, Norman M., "Site Contracting and IRB Review Processes: Parallel or Serial?", *Journal of Clinical Research Best Practices*, February 2015, https://www.magiworld.org/resources/journal/1671_Parallel.pdf

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