

## **Protocol Feasibility Process and Forms for Clinical Sites**

**By Rachel Sheppard**

For a site to perform well on a clinical study, it needs to conduct studies that are suitable. Starting a study that is impractical because of patient population, financial, resource or other reasons serves no one's interests. The best way to avoid failed studies is to not start them in the first place. The key to screening studies well is to carefully evaluate protocol feasibility. This article describes the protocol feasibility evaluation process employed by the University of Louisville, Office of Clinical Research Services and Support (OCRSS).

An effective protocol evaluation process has nine key components:

### **Create a straightforward process.**

The process must be clear and also flexible because the stages in site selection often vary by sponsor and can change unpredictably. Site qualification, sharing of the protocol synopsis, CDA execution, and protocol release occur at various times for each sponsor and CRO. A process flow map is very useful. Our feasibility process map is in Figure 1. Standard operating procedures (SOPs) are also useful.

### **Designate a driver.**

For a typical protocol at our site, representatives from five different functional areas play important roles in the process. One of these people must be responsible for driving the process. Identifying a process driver creates accountability for any stalls that may occur. It also removes any ambiguity in responsibility for completion of the process. In OCRSS, the regulatory specialist assigned to the protocol is responsible. This person is the primary contact for the sponsor and has the best information about the sponsor's expectations and timeline.

### **Identify the final decision maker.**

Ambiguity in who makes the final decision can delay the process and cause studies to be accepted without an explicit decision. For each study, identify who will decide whether to accept the study and be accountable for the decision. At our institution, in some departments, the principal investigator (PI) makes the decision; in others, division chiefs within the departments take the responsibility.

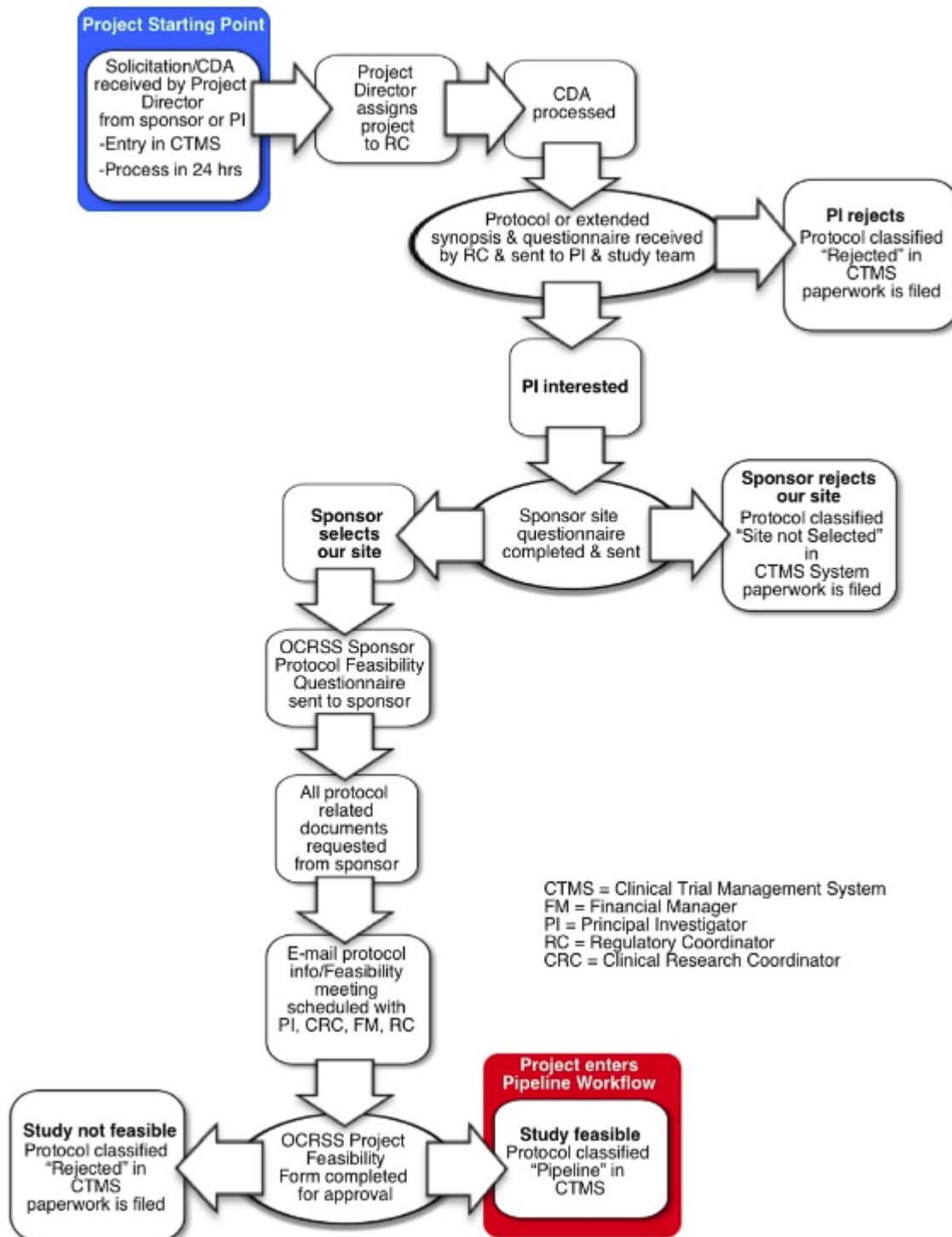
### **Educate everyone.**

A process map and SOPs will facilitate the process of educating the people who will be involved. People involved only occasionally, such as PIs, should be able to find and read the documents without special training classes. It also helps to build instructions into the documents.

**Make the process action-oriented.**

Keep the process moving by identifying follow-up actions, deadlines and responsible parties at each step. For example, if feasibility is discussed at a meeting, what is the next step? If there are questions about information from the sponsor, who follows up? What triggers the next meeting for discussion? Who notifies the sponsor of acceptance or rejection?

**Figure 1. Feasibility Evaluation Workflow**



### **Track progress.**

Maintain a database or spreadsheet with up-to-date information on the status of each protocol evaluation, including metrics that flag processes that need extra attention.

### **Ask sponsors for the information you need.**

Much of the information that drives costs, personnel effort, and the ability to enroll subjects is not contained in the protocol, informed consent template, draft contract, or proposed budget. We therefore use a questionnaire to collect this information from sponsors. ([http://www.firstclinical.com/journal/2010/1002\\_Feasibility\\_Questionnaire.pdf](http://www.firstclinical.com/journal/2010/1002_Feasibility_Questionnaire.pdf)) We limit the questions to those we consider the most important and try to make the form as easy to complete as possible. We send the questionnaire to the sponsor upon site selection, unless there are unusual circumstances.

We request information on training requirements, type and size of CRF, monitoring schedule, timeline, study-wide progress, prohibited medications, and other topics. Most sponsors supply the information quickly and without complaint. In fact, they often compliment us on asking for the information. They rarely consider the information proprietary. In many cases, they just did not understand what information we needed. If more sites start to request such information from sponsors, more sponsors may start to provide it with the protocol.

We often discover important information in the questionnaires. For example, we once learned that a four-month enrollment period included one month for obtaining IRB approval. With only three months, at best, for enrollment, we did not conduct the study. Another time, we learned that the 30 minutes allowed for eCRF entry at each visit would involve 293 web pages. The budget was adjusted.

### **Present information clearly.**

We compile the collected information in a six-page form ([http://www.firstclinical.com/journal/2010/1002\\_Feasibility\\_Form.pdf](http://www.firstclinical.com/journal/2010/1002_Feasibility_Form.pdf)) with eight sections:

- **Impact.** Completed by the PI, this section covers how the protocol could improve patient treatment and enhance the reputation of the investigator or institution.
- **Protocol.** Completed by the PI and clinical team, this section solicits information on any experience with this type of protocol, how the protocol fits with standard practice and ethics for treatment, subject compliance issues, and specialized resources needed to conduct the study.
- **Enrollment.** Completed by the clinical team, this section asks specific questions about eligibility criteria to identify any issues that might interfere with enrollment.
- **Procedures.** Completed by the PI and clinical team, this section requests information about the procedures to be performed. In particular, are there any non-standard procedures that are hard to tolerate, schedule, or perform? This section also addresses reimbursement, ethics and compliance issues.
- **Sponsor expectations.** Completed by the clinical team and regulatory coordinator, this section summarizes the sponsor's timeline and enrollment expectations.
- **Sponsor/CRO.** Completed by the regulatory coordinator, this section includes any previous experience with the sponsor/CRO and its management style, and any information needed by our IRB.

- **Resources.** Completed by the clinical team and regulatory coordinator, this section addresses staff hours, ancillary department requirements, training issues, and sponsor-supplied resources.
- **Financial.** Completed by the financial manager, this section includes information about the budget template, previous negotiations and contracts with the sponsor, and the sponsor's solvency.

Organizing the information in this fashion facilitates evaluation of the protocol in the following ways:

- All functional areas that affect site performance receive attention.
- Information gathering is assigned to the most qualified personnel.
- Each section can have its own recommendation.
- There is accountability for the information to be as timely and accurate as possible.

This form also contains the area for signatures to approve the study.

### **Evaluate the process periodically.**

Over the past six months, we have changed the process (to respond to timing issues) and the forms (to include more information). Metrics about timelines can point to areas for improvement.

### **Conclusion**

Feasibility evaluation typically consumes about 25-30 work hours for all involved parties. It adds about two weeks to the larger process of starting a project. The time is a concern, but well worth it considering the unsuitable protocols we avoid and suitable protocols we accept. In general, we accept about 60% of protocols as feasible.

### **Author**

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