

JOURNAL OF CLINICAL RESEARCH BEST PRACTICES

Vol. 3, No. 7, July 2007

"Can You Handle the Truth?"

Process Flowcharting for SOP Development, Implementation, Training and Maintenance

By Lorrie D. Divers

Standard operating procedures (SOPs) are "detailed, written instructions to achieve uniformity of the performance of a specific function."¹ SOPs help ensure consistent high quality and regulatory compliance. However, developing SOPs for complex cross-functional processes – as most clinical research processes are – can be confusing and intimidating. Training and implementation are additional challenges, especially when standardization and change are involved. By helping people visualize processes, flowcharting is an effective tool in developing, training, implementing and maintaining clinical research processes ranging from protocol development to subject recruiting to data management.

What is "Process Flowcharting"?

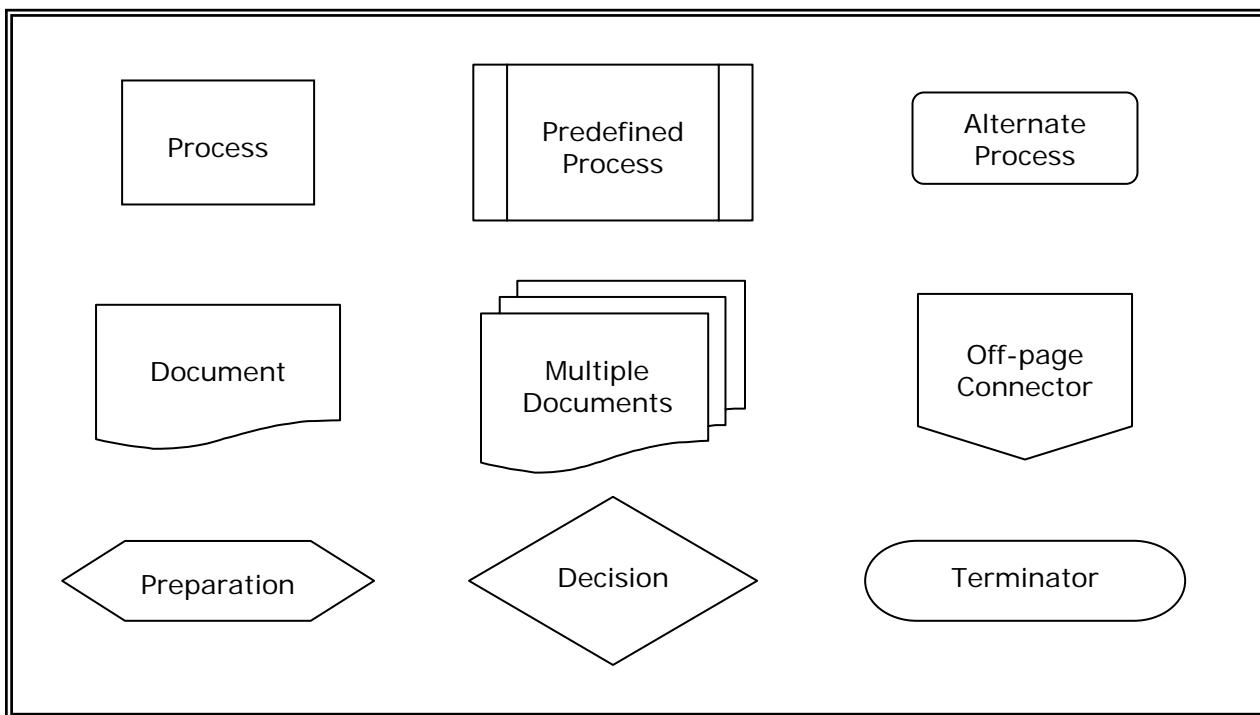
Process flowcharting is "a method of graphically describing an existing process or a proposed new process by using simple symbols, lines and words to display pictorially the activities and sequence in a process."² A process flowchart is simply a picture of how something gets done or produced from start to finish. That something might be a product or a service and might involve a single person or many people from multiple departments and even organizations. For example, developing a new drug or medical device is a huge, highly complex process that consists of smaller sub-processes such as conducting a clinical trial, which, in turn, consists of smaller sub-processes such as performing an IRB review, which, in turn, consists of smaller sub-processes such as developing an informed consent form. Regardless of the size and complexity of a process, it can be described from inception to completion in one or more diagrams.

There are different types of process flowcharts:

- Simple block diagrams can readily provide a high-level overview.
- Formal American National Standards Institute (ANSI) flowcharts show detailed interrelationships with the standardized symbols in Figure 1.
- Functional flowcharts map a process as it crosses functions or departments and highlight opportunities for process improvement such as duplications, bottlenecks, excessive hand-offs, and opportunities for parallel vs. serial processing.

Because of the complexity and number of functional roles and areas involved in most clinical research processes, functional flowcharts, also called swimlane flowcharts, are generally the most useful for illustrating the majority of clinical research processes.

Figure 1. Standard Flowchart Symbols
(Available in the Microsoft Drawing Toolbar)



Defining the Customer

A critical component of business process flowcharting is identifying the “customer” – the recipient of the product or service produced by the process. There may be more than one customer. “To identify your customers, you need to find out who receives or benefits from the output of the process.”² Customers can be internal or external to your organization and may directly or indirectly receive the results of the process. For example, the direct customer for an informed consent form is the potential research subject, while the indirect customers include the clinical investigator, the IRB, and the government regulators. Another process cannot be a customer, but the person where that process starts can be. A process can have timelines, but timelines cannot be customers. Ultimately, every process results in a specific individual or organization receiving or benefiting from the specific results of the process.

Understanding who the customers really are and their needs is critical to designing effective processes. For example, potential study subjects want informed consent forms that are informative and easy to understand, while IRBs also consider regulatory compliance and protection of research subject rights. For the legal department, risk management may be most critical. “Unfortunately, the customer focus approach almost exclusively encourages a pragmatic, heads-down, make-the-next-guy-happy mentality. This may not actually help your organization at all, if the focus should be at a much higher plane.”³ The ethical principles that guide clinical research dictate that the needs of the ultimate recipient of most clinical research processes – the research subject – and protection of their safety, welfare and rights is paramount. Similarly, while it could be argued that the customer for a protocol is either the investigator or a regulatory agency, failing to consider both the investigator’s need to easily follow the protocol and the regulatory agency’s need for appropriate information may result in harm to human subjects and possibly to patients who might receive the marketed product in the future.

The Process of Flowcharting

Example Flowcharts A to C below illustrate the evolution of an actual flowchart for the process of a clinical research investigator preparing and submitting an informed consent form to an institutional IRB:

- A. After reading existing SOP and interviewing participants
- B. After group discussion
- C. After group redesign

A good place to start flowcharting is to collect information by reading any existing documents that describe the process. These documents might include SOPs, work practice instructions and guidelines, and job descriptions. Additional information can be elicited by interviewing or surveying the individuals involved in the process. It is best to then gather everyone involved in a room. While it may be difficult to include a potential study subject at this point, conflicts in process design and improvement should be resolved by considering their interests as the critical direct customer.

The objective of the meeting is to create an accurate – not artistic – picture of the process. In a group discussion, the interplay among participants often highlights important details and inconsistencies. It also helps participants see how the steps they perform fit into the big picture. It is not uncommon for people responsible for part of a process to focus on moving paper from their inbox to their outbox, without understanding how their actions affect other steps in the process. For example, stapling a document that will be photocopied in the next step, wastes the time of two people and may cause paper jams in the copier.

Unroll a long piece of paper and tape it to the wall so the results of the meeting can be saved. Give everyone a pad of 3" x 3" or larger self-adhesive ("sticky") notes. Ask them to write individual steps on the notes, including a verb and a noun, e.g., "Review document for regulatory compliance." At this point in the exercise, it is important to identify what is done, rather than who does it. Therefore, focus on tasks, not on people or departments. Table 1 sets forth the basic rules for effective flowcharting. A task-oriented approach that focuses on individual process steps can be less intimidating, is easier for people to grasp than elaborate narrative, and encourages involvement by all participants in the room. By leaving out until later who performs the steps, issues of competence, responsiveness, personality and ownership are minimized.

Table 1. Fundamentals of Flowcharting

| | | |
|------------|---|---|
| BE CLEAR | Create one box or symbol for each function or action in the process. Use a verb and an object. "Do" example: Shred the purchase order form. | Do not include who or how. Do not use a subject. "Do Not" example: The secretary will use a shredder to confidentially discard the purchase order form. |
| BE LOGICAL | Give an input and an output to each step. The diagram should "read" from right to left or from top to bottom. | Multiple inputs/outputs indicate steps that need to be broken down further. |
| BE DIRECT | Use prominent arrows to indicate flow of process. Indicate decision points clearly with only one input; more than one result/output is possible. | Do not sacrifice clarity just to fit the diagram onto one page. |

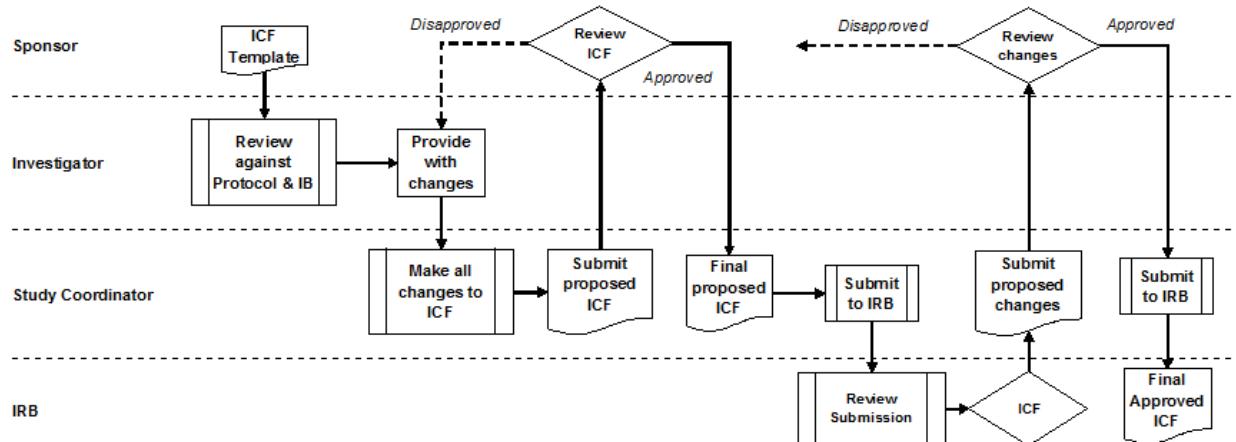
Place the notes on the paper in logical order. Using the notes rather than verbal narratives minimizes missing or extraneous steps and incorrect sequencing. Flowcharts can describe processes at various levels of detail, so it is important that any given flowchart maintain a consistent level. In general, to be clearly followed, a flowchart should have no more than 25 steps. If there are more than 25 steps, a simple, high-level flowchart and then more-detailed flowcharts for sub-processes may be more effective. Verbally review the flow to make sure all participants agree that the notes are arranged correctly. Then draw arrows between the notes to document how the process flows from one step to the next.

During the process of drawing the flowchart, it is common for the group to identify ways to improve the process. Someone will say, "Why do we have so many different ways of producing the document? It would be so much easier if we all did it the same way!" While people are working on documenting their current tasks, these ideas for improvements should be placed in a "parking lot" – an area on the wall chart or on a separate flip chart set aside for collecting them – until the current process is documented. This discourages problem-solving before knowing what the whole problem – in other words, the process – actually looks like.

Following completion of the current process flowchart, the group may want to discuss process improvements. There may be no need to draw before and after flowcharts. Simply documenting the changes in written notes attached to the current flowchart or writing changes on a different color note and re-arranging as appropriate may be sufficient, unless the process is being radically re-designed.

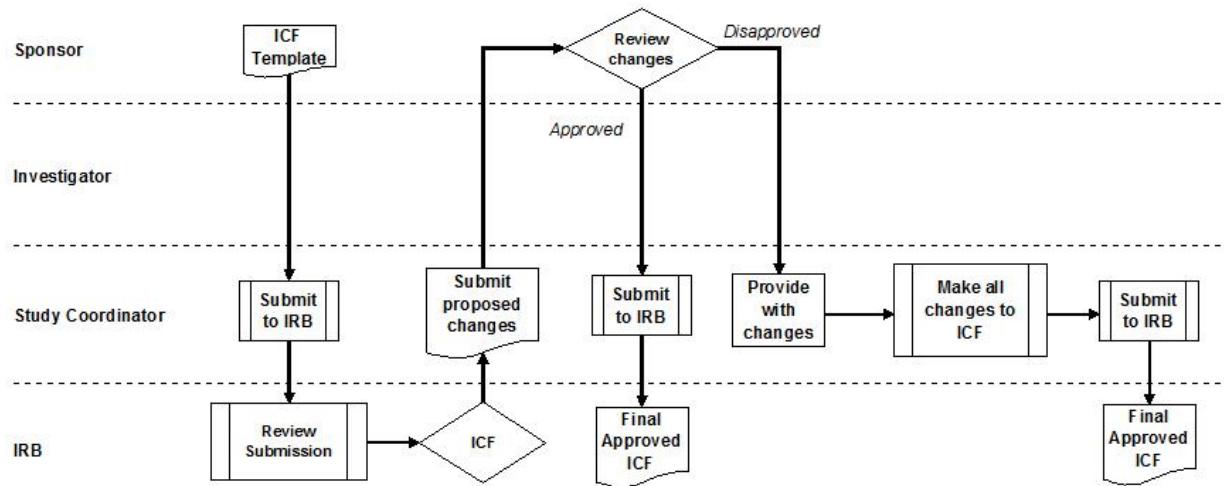
After the meeting, use Microsoft Excel, PowerPoint, Visio or another software tool to create an electronic version of the flowchart. One advantage of Excel is that you can include explanatory notes at the bottom of the worksheet. The following example flowcharts were produced in Excel.

Example Flowchart A: Based on Current SOP and Individual Interviews



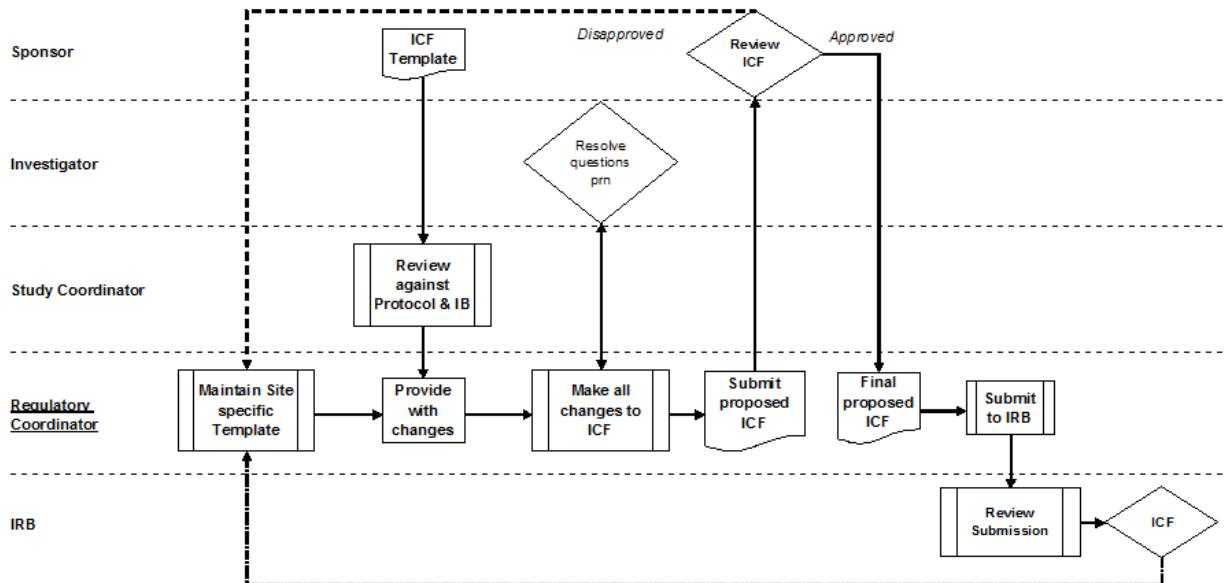
This flowchart describes the perceived process – what the current SOP describes or what individuals describe – for developing a site-specific informed consent form using a sponsor-provided template. However, discussion with the IRB chair indicates that ICF documents coming to the Board for approval are missing all the institutional requirements, don't have the right contact information, have inaccurate HIPAA information, etc. Furthermore, sponsors are complaining about delays in IRB approval. This situation would benefit from gathering representatives from all involved areas to review and discuss together (see Example Flowchart B).

Example Flowchart B: Based on Group Discussion



Representatives from each involved area gathered together to review the process diagrammed in Example Flowchart A. Several study coordinators and investigators indicated that they had been submitting the sponsor-provided template directly to the IRB, for reasons varying from lack of time to lack of expertise or awareness about institutional ICF document requirements. This would explain (i.e., be the root cause of) both the IRB chair's and the sponsor's complaints.

Example Flowchart C: Process Redesigned by Group



Based on group discussions (see Example Flowchart B), a process that relies on a centralized resource (a Regulatory Coordinator) to process ICF documents, has been created for this high-volume clinical research site. A new function for the Regulatory Coordinator is to maintain a site-specific template that will contain standard language that meets all institutional requirements and commonly used text that has been approved by the IRB (for example, risks and discomforts in lay terms). This template will facilitate more rapid turn-around time for IRB submissions and approvals, as well as discussions with

sponsors regarding required standard text (i.e., the research-related injury clause) that the institution will not negotiate.

Flowchart to SOP

The first SOP to write, and thus, the first flowchart to create, is for the SOP on developing, disseminating and maintaining SOPs. With a process flowchart in hand, it is a relatively simple matter to write a narrative SOP; just turn the picture into words. (See Table 2.) It is at this point that you assign process steps to roles – the who – and provide practical details – the how – where necessary. Use functional role descriptions such as “Head of Clinical Operations or designee” (to allow for delegation of tasks, if appropriate), rather than titles which may change, such as “Associate Director, Clinical Operations,” or the names of specific people, which might have to be changed frequently. Similarly, where possible, do not refer to specific elements of how the task is accomplished such as “by e-mail” unless this is critical to the process; “in writing” may be sufficient to describe how the study coordinator will be contacted and will permit flexibility where appropriate.

Clinical research is a highly-regulated activity. It is advantageous to ensure that the process you design is compliant with the regulations by including a regulatory, procedural compliance, or quality assurance representative in the group meeting. In addition, after the meeting, the draft SOP should be reviewed for regulatory compliance and against all available guidance materials. Regulatory citations and interpretation notes, if necessary, should be incorporated into the SOP.

Table 2. Example SOP Text (refer to Flowchart A)

| Step | Responsibility | Tasks |
|-------------|-----------------------|--|
| A. | Clinical Investigator | <ol style="list-style-type: none">1. Review sponsor-provided ICF template against protocol and IB; note any errors, omissions and ambiguities.2. Forward ICF template, protocol and IB to Study Coordinator. |
| B. | Study Coordinator | <ol style="list-style-type: none">3. Review ICF template and Clinical Investigator notes.4. Review ICF template for compliance with IRB requirements.5. Contact sponsor regarding any questions and issues.6. Prepare site-specific ICF using sponsor-provided template, with changes as identified in steps 1 and 4.7. Send proposed site-specific ICF to sponsor contact for review and acceptance. Negotiate as necessary.8. Document sponsor acceptance in regulatory binder. |

SOP Implementation, Training and Maintenance

Do not discard the flowchart when the SOP is done. It continues to be a handy tool:

- Include all or part of the flowchart in the SOP to explain complex processes.
- Use the flowchart when implementing a new process or modifying an existing one. It is especially useful in helping people understand how their tasks fit into the overall flow.
- Use the flowchart in SOP training. Some people understand pictures better than words; some understand words better than pictures. Complex processes benefit from both words and pictures.
- SOPs can become out of date and should be reviewed and updated periodically. The electronic flowchart can be updated easily. Note, however, that it may be easier to start with a blank piece of paper if major revisions are anticipated.
- Use the flowchart as a tool in quality assurance, to make sure the process is being followed as defined. By revealing important details and relationships that may be hard to see in the narrative SOP, the flowchart can help you remember why a process is designed the way it is, or what may have been left out accidentally. If the SOP is not being followed, use the flowchart to diagnose problems and bring the SOP and actual practice back into alignment.

The Big Payoff

Process flowcharting saves time and improves the quality of developing, implementing, training on, and maintaining SOPs. A valuable additional benefit is the contribution it can make to improving the processes themselves by identifying opportunities to:

- Simplify excessive complexity, unnecessary work, and too many hand-offs.
- Open up bottlenecks with tools, training or additional personnel.
- Eliminate inefficient duplication and consolidate fragmentation of effort.
- Move steps such as review and approval early or later in the process and make them parallel rather than serial.

After a bit of practice, process flowcharting becomes very easy. It does not require specialized expertise in the process of flowcharting, only in the processes of clinical research.

References

1. International Conference on Harmonization (ICH) E6 Guideline on Good Clinical Practice
2. "Business Process Improvement – The Breakthrough Strategy for Total Quality, Productivity, and Competitiveness", HJ Harrington, McGraw-Hill, Inc., 1991
3. "Not at Your Service", RS Waife, Applied Clinical Trials, August 2004

Author

Lorrie D. Divers is Sr. Clinical Quality Specialist, Global Clinical Programs, at Bausch & Lomb. Contact her at 585.338.5419 or lorrie_d_divers@bausch.com.