

Study Coordinators from Hell

By Tammy L. Morton-Taylor

Having been both a study coordinator and a site monitor, I found the article "Site Monitors from Hell," by Fran Dickson and Ruth Steele, to be accurate and fair.¹ Like site monitors, study coordinators have very challenging responsibilities and often work in difficult environments without much support from the rest of the organization. In the spirit of fairness, this article discusses the Study Coordinator from Hell (SCFH).

SCFH Behaviors

How do you know if a study coordinator qualifies as a SCFH? Common SCFH behaviors include:

- Is unfamiliar with the protocol.
- Promises to have all the case report forms (CRFs) completed prior to your monitoring arrival, then hands you CRFs that are only partially completed.
- While trying to finish documentation that should have been completed prior to the visit, constantly interrupts your work for "clarifications."
- Cancels the visit that morning or, even worse, tells you when you arrive on site that he or she has no time for you today.
- When you arrive on site, tells you that they will be unavailable all afternoon, so if you want him or her for anything, it will have to be before lunch.
- Halfway through the day, tells you that the principal investigator (PI) cannot keep your scheduled appointment or sign documents because he has already left for the day.
- Complains to your manager or the sponsor rather than first attempting to resolve the issue with you directly; or insists on talking to your manager before correcting errors.
- Refuses to take responsibility for his or her errors, becoming defensive and argumentative; tells your manager that the errors are a result of your instructions.
- Claims an erroneous value is correct, even if he or she can't find the source in the subject's medical records.
- Blames you for his or her own errors, arguing that you've instructed him or her incorrectly.
- Adds signature dates to informed consent forms to be helpful.
- Signs the PI's name on paper CRFs, or logs in as the PI to sign eCRFs because PI is "very busy."
- Talks to you throughout the visit about how he or she wants to be a site monitor.
- Speaks disrespectfully about coworkers, other site monitors, the sponsor (if you are with a CRO) and the study.
- When study product does not reconcile, informs you that the clinic's regular inventory was used to enroll a subject because no study product was available that day.

- Explains that the regulatory binder is a mess because there has not been time to file documents properly.
- Waits until you are on your way out the door after a multiday visit to ask if the death of a subject (whom you were not reviewing that visit) should be reported as a serious adverse event (SAE).
- Tells you the IRB requires only annual reporting of SAEs despite the written policy.
- Keeps all study subjects' lab work in a separate folder and refuses to place it in the appropriate subject binder.

Dr. Jekyll and Ms. Hyde

In the middle of my first visit to a site, the investigator poked his head through the conference room door to ask if there were any items that required his attention. Knowing that it would be my only opportunity to speak with him that day, I took the opportunity to discuss the priority findings that would need to be addressed prior to my next visit. I concluded our conversation by indicating that there were other items to address, but that I would discuss them in detail with his study coordinator. During our meeting with the study coordinator, we reviewed items to be reconciled and spent almost two hours working through the many corrections required on the CRFs that resulted from a few complicated SAEs. A week after I sent the follow-up letter, the sponsor called to tell me that the study coordinator had complained about me, stating that the follow-up letter included action items that we had not discussed during the visit. The study coordinator was correct that I had not discussed them with her, but I had discussed them with the PI. She went on to challenge the items with explanations that differed from what I had learned during the visit. I gave the sponsor my side of the story. The issue was eventually resolved, but it could have been avoided if the study coordinator had talked to her PI and me before complaining to the sponsor.

Remedies

A site monitor's job is to go into someone's "home," look for things to correct, tell them about it, and then write a report and follow up letter about the errors. It is not an ideal situation for building a friendship, especially if there are many errors. Therefore, handling a SCFH can be a challenging situation for even the friendliest, most seasoned site monitor.

A site monitor's first priority is to set a professional tone and establish expectations. Showing respect for the study coordinator is an essential part of a professional relationship. The site initiation visit is not only the best opportunity to train site personnel on the study, but it is also the perfect opportunity to work with the site to establish the monitoring expectations: what time of day you normally arrive, roughly how many subject's CRFs you will review at each visit, and the length of time intervals between visits. You can also find out the best method of communications for site visit confirmations, follow-up letters, enrollment logs, etc. via email, faxes or letters.

When working with a study coordinator who doesn't complete action items prior to your arrival, a bit of offered assistance will serve you well. Sometimes the site monitor can help the study coordinator with a task such as providing an outline for an IRB report. Ask the study coordinator what you can do to assist him or her. Generally, the answer is "nothing," but it does show study coordinators that you are on the same team and you are working

with them, not just giving them a list of things to do with their spare time. A little help truly goes a long way in building the relationship.

CRF completion, of course, is not an option for a monitor. However, when working with electronic data capture (EDC), site monitors have an advantage over paper-based trials: Site monitors can log onto the study system prior to the visit to actually see the state of readiness of the CRFs. If CRFs are not completed, the visit can be rescheduled. Even the best study coordinators may fall behind on their paperwork from time to time, but when it occurs at every visit, a conversation regarding timely CRF completion with the study coordinator must ensue. If that does not work, a non-judgmental mention of the problem to the PI is the logical next step: "Sally seems really busy; is it possible to get her some assistance prior to my next visit?" However, before taking the risk of creating a bigger problem, ask yourself if, for example, the study coordinator who routinely completes CRFs while you are on site, but does not slow you down, is really a problem or just an annoyance.

For the SCFH who frequently interrupts your work, establish set times to meet and discuss clarifications. Tell the SCFH that when interruptions occur, mistakes are made.

There are times when even the most available coordinator may be called away during a monitoring visit. If his or her absence prevents the site monitor from completing the visit, the site monitor must switch gears and come up with a plan to have all corrected data either sent to him or her (paper study) or completed to verify off-site (EDC). As long as the site monitor is clear about what steps must take place after he or she leaves, this scenario is generally acceptable and works well.

When working with a SCFH, it's a good idea to notify management of any situation that may be misconstrued or in which you may have erred. When your manager gets the call from the angry SCFH, he or she will already know your side of the story.

Knowing the written IRB policies and procedures, and even calling the IRB for clarifications, can enable the site monitor to explain shades of gray to the study coordinator and/or PI.

Listening to someone rant and rave about his or her problems is never pleasant. However, in order to remain a neutral party, the following line seems to work wonders: "Wow, you seem unhappy. You should speak with your supervisor and see if you can find a solution to the problem." When a study coordinator repeatedly asks about becoming a site monitor, you can offer information about how you got your first job monitoring, site monitor qualifications, and how to apply for a position at your company. Unless you are enthusiastic about the person, do not accept their CV to forward to a hiring manager at your company.

An inexperienced SCFH may have the best intentions when dating documents for the PI or a subject, and may not see the harm in entering EDC data for a busy PI. Early recognition of specific behaviors and working together to create a corrective action plan will usually establish good GCP compliance.

This industry attracts people who are intelligent, detail-oriented, take pride in their work, and enjoy keeping busy. Put a site monitor and a study coordinator who share these attributes into a room together, apply pressure, and sparks may fly. The bottom line is that we all need to be professionals. We need to recognize that we share the goal of getting life-changing therapies to patients. Well-conducted research makes this common goal achievable.

Reference

1. "Site Monitors from Hell," Fran Dickson and Ruth Steele, *Journal of Clinical Research Best Practices*, August 2008

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