JOURNAL OF CLINICAL RESEARCH BEST PRACTICES

Vol. 2, No. 6, June 2006 "Can You Handle the Truth?"

# Hiring, Training, Managing and Retaining Study Coordinators

**By Norman M. Goldfarb**

The workforce of a clinical research site includes one or more investigators and study coordinators, and may include a site manager and functional specialists in areas such as regulatory affairs, subject recruiting, contract and budget negotiation, data management, and administrative tasks. This article will focus on study coordinators, but is also largely applicable to other site personnel.

Before proceeding, we must define the study coordinator's role. To do that, we must first define the role of the principal investigator. At some sites, the principal investigator takes a hands-on role in actively managing and conducting clinical trials. More commonly, however, the investigator delegates study responsibilities other than the medical and safety aspects and regulatory requirements such as high-level oversight and reviewing and signing various documents. In this scenario, the investigator primarily serves as a resource to the study coordinator, who takes the study leadership role. Both approaches work, provided everyone is competent and the investigator is engaged with the study. In other words, the study coordinator can do most of the work and make most of the decisions, but the investigator cannot delegate everything; he/she must take his/her role – however limited – seriously.

## Responsibilities of the Study Coordinator

In the scenario where the study coordinator is the study leader, he/she typically contributes perhaps 90% of the site's time on the study. In addition to day-to-day work on the study, he/she is typically the site's expert on the protocol, the informed consent form, and most other aspects of the study. He/she is responsible for "making the study happen" and marshalling resources as required. As the person primarily responsible for the success of the study, he/she should play a major role in selecting studies to be conducted by the site.

The division of responsibilities between investigator and study coordinator in obtaining informed consent from potential subjects is often debated. The investigator is probably more qualified to explain the medical aspects of the study and has ultimate responsibility for the subject's safety and welfare. However, at most sites, the investigator has numerous other responsibilities that prevent him/her from knowing the protocol in detail and spending adequate quality time with the potential subject. If the investigator has a doctor/patient relationship with the potential subject, undue influence is essentially impossible to avoid. For these reasons, in the author's opinion, a qualified study coordinator is the better choice to lead the informed consent process, with the investigator's responsibility mostly limited to answering the potential subject's questions and making his/her own judgment as to the suitability of the potential subject for the study and the study for the potential subject. In addition, the success of the study largely depends on the personal bond that forms between the subject and the study coordinator, so obtaining informed consent is a good time to cement that bond.

## The Ideal Study Coordinator

The ideal study coordinator:

- Has prior study coordinator and medical experience

- Is familiar with clinical research and medical terminology and concepts
- Meets all credentialing requirements required to perform clinical study activities
- Is responsible
- Has excellent communication and interpersonal skills
- Is detail-oriented
- Is flexible
- Works well both in a team and individually
- Is able to manage time and multitask
- Is honest
- Is punctual
- Has respect and compassion for subjects
- Holds him/herself to high standards

Three of these characteristics bear special mention:

- Study coordinators should have nursing credentials if the studies involve routine activities that require nursing credentials, and nurses are not conveniently available from the clinical staff. Appropriate training, but not nursing credentials, is required to take blood pressure readings, run EKGs, and draw blood. Opinion differs on whether medical training is required to obtain informed consent. In the author's opinion, it is not, provided training is appropriate and the investigator is available to handle medical questions.
- A study coordinator may be successful if he/she does not respect and have compassion for the study subjects, but these characteristics are hard to fake and the essential bond between study coordinator and subject is less likely to occur.
- Based on a recent time study by the author, study coordinators perform an average about 50 different activities each day.[1] Study coordinators who cannot manage their time in the face of constant distractions are unlikely to be productive.

**Finding a New Study Coordinator**

A site can obtain a new study coordinator from its organization's current staff or hire a new person from an external source. Assuming the internal candidate does not have coordinator experience and the external candidate does have it, the respective advantages in Table 1 apply.

**Table 1. Promote or Hire**

| Internal Candidate | External Candidate |
|---|---|
| Lower initial salary | Higher initial salary |
| Knowledge about the organization | Knowledge about the job |
| Knowledge of the candidate as a person | Knowledge of the candidate's expertise |
| Commitment to the organization known | Commitment to the job known |
| Training period required | Hits the ground running |

Both approaches have their advantages. Over the long run, a mixed strategy offers the best combination of organizational continuity and fresh perspectives. The most likely failure modes for an internal candidate are that the person (a) is thrown into the fray without proper training or (b) discovers that he/she simply does not have the aptitude or enjoy the study coordinator job. For example, study coordination involves much less patient contact and much more paper handling than nursing. The most likely failure

modes for an external candidate are that the person (a) does not have the qualifications expected or (b) does not fit well into the organization. For example, a person who is accustomed to working alone in a quiet office may not thrive in a large office shared by chatty people.

If the decision is made to staff the position from outside the organization, an employee or contractor may be engaged. Table 2 presents the pros and cons of each approach.

**Table 2. Employee or Contractor**

| **Employee** | **Contractor** |
|---|---|
| Probably long-term | Probably short-term |
| Relatively low cost | Relatively high cost |
| Fixed cost | Variable cost |
| Low-productivity transition period acceptable | Must contribute immediately |
| Preserves and incrementally | Contributes knowledge immediately |

Organizations with stable employees tend to outperform organizations in which the staff comes and goes, but an experienced contractor may be the only way to meet a short-term need. Also, he/she may significantly improve the organization's performance if he/she serves as a source of new knowledge.

New employees and contractors can be found many ways:

- Personal recommendations, especially from current personnel, often produce candidates who are relatively likely to succeed.
- Fresh graduates from clinical research educational and training programs, including experienced professionals who are changing careers, can offer diverse expertise and fresh ideas.
- Employees and contractors at other research sites may transfer over smoothly or reveal unfortunate deficiencies.
- Advertising can generate huge numbers of candidates that require a time-consuming winnowing process.
- Staffing firms can deliver excellent prescreened candidates or just warm bodies.
- Candidates can self-refer, i.e., just walk in the door.

Once the first candidate is identified, the selection process begins. If possible, it is much easier to pick the best candidate from a group than to determine whether or not to hire a single candidate in isolation. Evaluation methods include:

- Review candidate's curriculum vitae (resume') for education, credentials and work experience.
- Call candidate's references, preferably including independently identified references and secondary references identified by those the candidate provides.
- Interview candidate, preferably in a structured process that includes current study coordinators.
- Test candidate to measure knowledge objectively and systematically.

When the author managed a research site, he advertised for candidates with at least two years of experience, screened their resumes, and telephone-interviewed the most promising ones with at least one year of experience. From an inventory of 50 questions, he selected questions that were most appropriate for each candidate. In an attempt to set the candidate at ease, he started with four very basic questions:

- What does "GCP" stand for?
- What does "CRF" stand for?
- What does "SOP" stand for?

Over half the candidates missed at least one of the questions, and some missed all of them. Although they may not have been exposed to SOPs – standard operating procedures, they had surely been exposed to GCP – Good Clinical Practice – and CRFs – case report forms. The errors thus probably reflect the inability to handle even minimal pressure or a fundamental lack of curiosity, problematic traits for a study coordinator.

A trial period during which the new employee is "on probation" is unnecessary with "at will" employees who can be fired at the employer's whim. It can, however, facilitate a useful orientation and evaluation period.

**Training Study Coordinators**

Study coordinators continually face new situations that require the interpretation of a complex web of regulatory, legal, medical, ethical, and professional factors. Training enables the study coordinator to deal with these situations correctly and efficiently.

All too often, a site hires a new coordinator to replace one who left some time previously. The manager walks the new coordinator to the old coordinator's desk – piled high with neglected study documents – and says, "Here you go. If you have any questions, just let me know." Needless to say, a training-intensive transition period is more likely to yield positive results.

Training begins with the motivation to learn. A study coordinator who does not want to invest time and energy learning is, at best, a mediocre study coordinator.

There are numerous sources of training and information for study coordinators, including many that require no cash expenditures:

- Websites
- Magazines, journals and books
- Seminars and conferences
- Degree & certificate programs
- On-the-job, "in-service" (i.e., internal seminars), and cross-training (e.g. between lead and back-up study coordinators)

**Table 3. Evaluating Training Programs**

| |
|---|
| Level 1: Did the students find the training worthwhile? |
| Level 2: Did they learn the material? |
| Level 3: Did they remember the material? |
| Level 4: Did they implement the material? |
| Level 5: Did implementation benefit the organization? |

Some of these sources are more useful than others, as measured by the methods in Table 3.

There is too much for any new study coordinator to digest in one massive dose, so a continuous training process is essential. Mentoring, cross-training and periodic in-service training can be very effective. In-service training can be conducted by internal personnel. Also, site monitors can be drafted to teach appropriate topics. Shared training based on the site's standard operation procedures promotes consistent, presumably high-level, performance.

Certifications and diplomas demonstrate learning achievement. However, taking courses for the sole purpose of obtaining or maintaining certification is missing the point.

**Managing and Evaluating Study Coordinators**

Managing and evaluating study coordinators can be very difficult or very easy. Standard good management practices, e.g., regular performance reviews, apply, but management needs to understand that the job of a study coordinator is very different from that of a practicing physician or nurse. The daily routine of most practicing physicians and nurses largely follows a standard pattern:

- Nurse escorts patient into exam room and takes vital signs.
- Physician enters exam room and conducts visit.
- Patient leaves.
- Office collects payment or invoices third-party payor.
- Repeat.

The study coordinator's day is very different. He/she may start the day planning one set of activities but spend the day on an entirely different set. All of these activities may be essential, but none of them may directly generate revenue. (Roughly 80% of the time a study coordinator spends on a study is not billable per the study budget.[2]) The initial reaction of the study coordinator's supervisor is to question the productivity of the study coordinator; how is the site going to pay the bills if no revenue is being generated?

Every day on every study is different, so it is almost impossible to manage a study coordinator's priorities, compare performance across study coordinators, or meaningfully measure performance with activity-based (as opposed to results-based) metrics such as number of studies, number of subjects, or number of study visits. These challenges are magnified if the manager does not have personal experience as a study coordinator and deep knowledge of the regulations, tricks-of-the-trade, etc.

Managing a study coordinator becomes very easy once the manager understands that the only person who can manage the details of the study coordinator's work is the study coordinator him/herself. Of course, this approach works only with good study coordinators. Rather than micro-managing the study coordinator, the manager is better off focusing his/her efforts on (a) finding and developing good study coordinators, (b) defining clear higher-level objectives, and (c) serving as a resource and facilitator.

The most effective metric for measuring study coordinator productivity is contribution to profit. Although no two studies are directly comparable, relatively time-consuming and difficult studies generally pay more than relatively quick and easy studies. The marketplace thus roughly adjusts for the differences between studies. Empowering study coordinators to accept or reject the studies they conduct gives them substantial control over their own performance. If the organization wants the study coordinator to conduct a loser study, financial adjustments can be made so the coordinator gives it fair attention.

Feedback from subjects and site monitors is worth collecting for a variety of reasons. However, the data is biased because subjects and site monitors often want to protect the study coordinator and not create bigger problems for themselves.

**Compensating Study Coordinators**

It is a rare manager who deliberately creates an unfair compensation program. Concepts of fairness, however, vary considerably. There are two types of compensation fairness:

- Internal equity means that all employees are compensated fairly based on their contribution, seniority or other consistently-applied measurements. Making the big assumption that everyone agrees with the measurement system and each employee's performance, management should, theoretically, be able to post a list of all employee salaries without causing an uproar.
- External equity means that employee compensation is consistent with the marketplace. Pay too little and employees leave; pay too much and the organization goes out of business. It is a law of nature that employees can always find anecdotal evidence that they are underpaid. The easiest way to monitor compensation in the local marketplace is to conduct a continuing program of interviewing potential employees and asking them about compensation. This approach has the valuable side benefit of pre-qualifying candidates in case a new position opens up or a current employee departs. Staffing firms should also be able to provide useful guidance about market prices.

Depending on an organization's culture, compensation will be more or less based on individual vs. group performance. A balanced strategy is optimal: Err on the side of individual compensation and employees start competing with each other; err on the side of group compensation, and individual accountability is lost and top performers leave the organization.

The most common compensation mistake made by clinical research organizations is to reduce employee compensation to recover training costs after training is completed. Other organizations, unburdened by these sunk costs, can easily hire away study coordinators with higher compensation that reflects the employee's true value.

Incentive compensation can motivate study coordinators to accomplish the organization's objectives. It is, however, extremely treacherous: Pay extra for enrollment and retention may suffer. Offer a cash prize to the best performer, and the others may resent him/her.

Although the practice is declining under closer regulatory scrutiny, some sponsors attempt to usurp management's role by offering incentives directly to the study coordinator. In the author's opinion, the best approach is to accept these incentives on behalf of the organization as a whole and use them for training or group social activities. This approach requires management to address potential conflicts of interest for the organization as a whole. If the incentive does, in fact, change the organization's behavior, there may be an ethical issue.

**Retaining Study Coordinators**

Once a site has a good study coordinator in hand, retaining that person becomes a top priority. Standard management practices apply, with special emphasis on empowering the study coordinator. In other words, give them authority consistent with their responsibilities. Good study coordinators largely manage themselves. Disempowerment is deeply frustrating and may be insulting to many good study coordinators.

**References**

1. "Clinical Research Terminology Codes: What We Do and How Much It Costs", Norman M. Goldfarb, Journal of Clinical Research Best Practices", March 2006.
2. Ibid.

**Author**

Norman M. Goldfarb is Managing Director of First Clinical Research LLC, a provider of clinical research best practices information, consulting and training services. Contact him at 1.650.465.0119 or ngoldfarb@firstclinical.com.