



Behind Every Great Principal Investigator . . .

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This issue of *The Monitor* is focused on “Clinical Trials: The Investigator’s Perspective.” I could discuss the importance of the investigator’s level of involvement in trials in relation to the on-time, on-budget delivery of quality data in an environment that maintains the volunteer’s safety as the highest priority. Of course, such expectations are familiar to, and should be highly valued by, any principal investigator (PI), but we all know that meeting them would not be possible were it not for another pivotal person on the clinical research team—the clinical research coordinator (CRC).

From beginning to end, the CRC is often charged with ensuring that attention is paid to all of the aforementioned factors in a successful study, and so much more, be it an industry-sponsored or investigator-initiated one. Certainly, from the PI’s perspective, the CRC is the life blood of any study. If you don’t believe me, ask any study coordinator why a study isn’t enrolling and you’ll learn the real story.

I am proud to say that at the beginning of my almost 20 years of involvement in clinical research, I was first and foremost a study coordinator, but officially gaining that title took some doing. Back in “the old days,” the gist of the titles that I carried, like those of many of my colleagues, evolved from Dr. Dan’s nurse, to Dr. Herr’s study nurse, to nurse coordinator, and finally to CRC, a title that ACRP pioneered as long ago as 1990 through its first Job Analysis Survey, which was used as background for developing our certification program for coordinators.

So, as a former CRC who worked with investigators and who now employs many CRCs, I understand the critical nature of what is often an undervalued and undercelebrated position by many in the industry. Although it is the PI that signs the 1572, CDA, investigator agreement, and a whole host of other documents, I fervently hope that every single PI does this with appreciation for the fact that the CRC working alongside him/her is an equally qualified, professional clinical research team member. With that knowledge, the PI can sign all manner of forms with confidence that all of the I’s have been dotted and T’s crossed (in black ink, no less).

In some cases, CRCs may come to feel such a great degree of responsibility for, and pride in, their studies, study volunteers, and PI’s that the CRCs will, on occasion, unknowingly overstep their role and responsibilities in pursuit of some benefit to the study or the volunteers that is more appropriately part of the PI’s role. However, no amount of qualification and commitment on the CRC’s part should at any time allow a PI to feel comfortable abdicating such responsibility, regardless of how close the PI-CRC relationship.

But how to know when the line has been crossed? With regulations and guidances that leave much to the imagination, I embrace and appreciate that even the FDA saw the need for clarity surrounding this topic and last May and issued a draft Guidance for Industry on “Protecting the Rights, Safety, and Welfare of Study Subjects—Supervisory

Responsibilities of Investigators” for public comment. The draft guidance clarifies the responsibilities of investigators in clinical trials conducted under 21 CFR parts 312 and 812. Among other issues, it provides recommendations on how investigators should provide adequate supervision of those to whom any tasks are delegated, which ties in to matters of the qualifications, training, and oversight of these persons.

The tone of much of the content of the draft guidance suggests that everyone has come to expect and rely on the CRC as the gatekeeper to the study conduct—maybe too much so in some instances—and it seems an appropriate time for some clarification to remind PIs of the responsibility they’ve signed on for.

Although the final version of the guidance has not, as of this writing, been released, I, along with APPI President Ihor Rak, MD, and ACRP President and CEO Thomas L. Adams, CAE, submitted comments in July on the draft guidance on behalf of our membership. In part, we stressed in our comments that investigators should ensure that both they and their staff have adequate training and certification in areas that are not only medical in nature, but also those that are related to human subject protection.

Taking into account the concerns that we have as an organization related to the PI-CRC relationship and my own con-

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cerns from experience, I am discouraged when I hear from CRCs that their requests for education or certification support are not recognized or supported by their employers. It’s no surprise that the number one reason for this denial is cost—involving the cost of the CRC being out of the office for a course, the cost of the course itself, doubts about the return on investment for the PI, and my personal favorite, the PI who asks “What if I provide you this training and you leave?” As I wrote in an earlier column, the CRC’s answer to that is “What if you don’t and I stay?”

Mixed into this complex cauldron of needs and responsibilities are other fac-

tors; sites are being asked to conduct their portion of the business of clinical research studies in a climate of increasing expenses (for everything, not just training), mounting workloads, and rising expectations from regulators, IRBs, sponsors, and CROs. It is no surprise, therefore, that one of the first “luxuries” to be cut from a site’s budget is often training dollars for the staff. Thus, although it is the responsibility of the PI to ensure that the staff is trained, and we do not need any guidance document to tell us that, we cannot deny that a host of conflicting financial burdens and time commitments can make it difficult for sites to obtain the training resources to do what they know is right for everyone involved.

Reading between the lines, PIs who intend to faithfully follow the FDA guidance, when it is finalized, will no doubt recognize that doing so will incur costs. I am confident that the industry as a whole will realize this as well, and that PIs will be compensated fairly for these additional expectations. In the end, it is far more than just great PIs who will reap the benefits of keeping everyone’s responsibilities clearly delineated; it is also the great CRCs behind them, our great study volunteers, and ultimately all future patients who receive approved therapies because of this vital teamwork.

As always, I welcome your thoughts (ckp@rxtrialsinc.com).

ANNUAL CALL FOR COMMITTEE NOMINATIONS

ACRP is now accepting nominations for individuals to be appointed to one of the Association’s many valuable member committees. Committees play a vital role in the functions and services that ACRP provides to its members. Current members have the opportunity to serve ACRP and the membership through committee involvement, which offers chances to network with fellow researchers, to pursue special interests, and to make an impact in areas that are important to them personally.

ACRP’s Board Chair, CEO, and Department Directors will consider all submissions and select appointees for open committees. Final approval of appointments will be made by the Association Board of Trustees at its December 2007 meeting. Appointments are for two-year terms, beginning in January 2008.

All nominations must be submitted online by **November 2, 2007**. Please visit www.acrpreistration.org/nominations/committeeform.cfm to fill out a nomination form.

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Questions? Please e-mail Bonnie Wilson at bonnie@acrpnnet.org.