Contributed by Lynn Meyer, CCRP

LYNN MEYER, CCRP

IS YOUR INVESTIGATOR MEETING MISSING A CRUCIAL COMPONENT?

You are planning an upcoming investigators meeting. Going over your checklist, you check off sponsor, project manager, central laboratory, site coordinators, site monitors, principal investigators, and others involved in the research. Flights, hotel accommodations, and meals also have been arranged. So what, if anything, is missing? Have you considered including a representative from the independent IRB you will be using? If not, perhaps you should add this to your checklist for your next meeting. A crucial component in planning an effective investigators meeting is representation from the IRB that will be responsible for reviewing the majority of investigators/sites.

THE INVESTIGATOR MEETING

The purpose of investigator meetings is to provide training and an opportunity to discuss modifications to the protocol and other study-related documents, such as case report forms, as well as to address and resolve other issues. Additionally, these meetings are designed to identify the responsibilities of each entity, enhance communications, build relationships, and ensure that expectations of each partner are met through mutual understanding. Personal interaction among all these entities is important to the success and efficiency of the study.

The goal of the sponsor, CRO, and laboratory is to establish a relationship with the sites as well as provide instruction and education while defining expectations; similarly, these are goals shared by the IRB. Enhanced communication with the sites benefits all parties in that expectations of the IRB also are clearly defined, not to mention the relationship building that occurs. The IRB is no longer the unknown partner in this collaboration.

HOW IRBS ADD VALUE TO THE INVESTIGATOR MEETING

Since submissions for review and approval of a site frequently occur before the investigators meeting, the role of the IRB at these meetings could include focusing on the reporting requirements of the IRB and timeframes for submitting reports to avoid noncompliance. When submissions have not previously been made to the IRB, the meeting offers an opportunity for the IRB to review the submission form with the principal investigator and/or site coordinator. The major delay in reviewing investigator submissions at the IRB is because of incomplete submissions. Pre-reviewing submission forms and requirements will help eliminate delays.

In addition, IRB participation in investigator meetings will help train coordinators about whom to contact at the IRB office, when items should be submitted to the IRB, where forms can be located, and the use of appropriate forms. The meeting could also incorporate information about how documents are processed and distributed by the IRB.

One of the potential benefits of including IRB representation in investigator meetings is document distribution, particularly when the IRB uses a Web portal for this function. Typically, the majority of individuals completing the information either fail to read the user instructions or do not fully understand what they are checking on the submission form. As a result, staff members receive telephone calls several weeks after an investigator is approved asking about the status of approval documents, which are posted and are available to them via the Web portal. Because electronic distribution occurs in real time, not to mention that the Web portal is equivalent to an electronic filing cabinet, all documents processed by the IRB can remain at the site until several weeks after the study closure notification is received. For these reasons, the goal is for all investigative sites to use this method, and with proper training this can be accomplished.

SITE INVOLVEMENT

Knowing that sites often work with multiple IRBs employing different processes, integrating the IRB into investigator meetings would allow sites to begin studies with an understanding of the expectations of the IRB. When the site's personnel know what to expect from the IRB, the result will be a more efficiently conducted study. Establishing and maintaining personal relationships is the core of good business and lasting relationships.

Attending and participating in these meetings is a service that an IRB should offer to clients. (In my 21 years of involvement with IRBs, we have received invitations to about four meetings, all of which were from one specific client.)

Incorporating IRB participation in investigator meetings can add enormous value to that process as well, while sponsors can use the knowledge and experience of the IRB to enhance training and education.

Among the potential benefits to all parties are increased efficiency and understanding, effective business interactions, and improved compliance.

So, the next time you are planning an investigator meeting, consider including the IRB in the process.

Lynn A. Meyer, CCRP, President, IntegReview Ethical Review Board, Austin, Texas. IntegReview merges ethics and technology to accelerate the IRB process while respecting and protecting human research participants. For more information, visit integreview.com.

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