IRB ADVISOR

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IRBs Can Learn to Make the Most of Central IRB Partnerships

The IRB at Inova Health System of Falls Church, VA, began working with a central IRB 15 years ago — long before the new Common Rule encouraged IRBs to designate an IRB of record for multisite studies.

Since then, the IRB developed a well-organized process for its partnerships with independent IRBs. The partnership is visualized as a triangular flowchart with the institution and human research protection program (HRPP) at the top, linked directly to both the principal investigator's study team on the left and the central IRB on the right.[1]

In 2016, 15% of the Inova IRB's protocols were reviewed by a central IRB. A year later, that proportion of central IRB reviews had more than doubled to 31%.[1]

This trend is expected to continue, and IRBs nationwide will increasingly rely on an IRB of record for reviews. The new Common Rule requires U.S.-based institutions that are involved in cooperative research to use a single IRB. This requirement has been delayed. *(For more information, visit: https://bit.ly/2JrtJRf.)*

In the meantime, IRBs can learn best practices in forming relationships with central IRBs. "I think it's very important to have a relationship with an IRB of record and to have a dedicated person reach out to them," says **Kathy Ababio**, BS, CHES, IRB manager for Inova Health System. "Having this relationship has helped us facilitate the process easier."

Communication is key to a successful partnership, says **Annika Shuali**, IRB coordinator for Inova Health System.

"Communication between our office and investigators helps everyone know what is expected," she says. "Communication between us and the IRB of record helps everyone get on board with the changes that need to be made."

Ababio and Shuali suggest the following best practice strategies for developing an optimal relationship with an IRB of record:

• Assign liaisons to work with the central IRB. Liaisons can be IRB coordinators who are responsible for communication and maintaining workflow between the institution's IRB and the central IRB. Inova has had liaisons since its first contract with a central IRB.

Shuali is one of the liaisons for the Inova IRB. "I have a broad role and also work as an IRB coordinator for some local studies at Inova," she says.

Inova has two liaisons who review submissions that go into the electronic submission system. They maintain consistency in their work through use of a one-page checklist with 12 submission tasks, including these examples:

- department impact forms indicating notification to other affected departments like pharmacy, nursing unit, radiology, as applicable;
- sponsor of study is listed and matches name listed on protocol and consent;
- research training completed and up to date for all investigators and research staff;
- financial disclosure forms are submitted for investigators and coordinators. Conflict of interest reviewed and referred to committee, as applicable;
- consent form(s) or waiver requested and documented appropriately;

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- consent form includes site-specific requirements, including subject injury language matching contract.

• **Screen studies for external IRB.** "When a study is submitted in the electronic system, we have a pre-review checklist that determines whether it is allowed to go to an external IRB," Ababio says. "That would be a study that does not have a vulnerable population, with a few rare exceptions."

Also, sponsored studies that are required to be reviewed by a central IRB would be accommodated, she adds.

"We are well aware of the change that's coming with the Common Rule, so we will be updating our policies," Ababio says.

• **Streamline processes.** Since starting its first central IRB relationship in 2003, the institution has made changes and updated as needed, Ababio notes.

"In 2016, we saw a need to make more drastic changes to increase our turnaround time in our metrics," she explains. "We found redundancies in our review and IRB of record."

After conducting a root cause analysis, they learned that the pre-review checklist included redundant tasks, she adds.

"We were looking for certain items to be met before we gave a cover letter to the IRB of record, and those same things were being done by the IRB of record," Ababio says. "So there could be delays."

To streamline the process, they stopped performing the same tasks as the IRB of record.

"We streamlined the process and allowed studies to go to the IRB of record within 48 hours," Ababio says. "The study team will send the cover letter, which we changed to an acknowledgement letter."

The IRB conducts a quick post-approval look at the informed consent to confirm that all Inova-specific language is intact and other requirements are met.

• **Agree on informed consent language.** Investigators use sponsor templates as the main part of the consent form and include information about informed consent for research purposes and the investigator's specific contact information, as well as contact information for Inova IRB, Shuali says.

"If people have questions they want to ask us about research studies and injury compensation, they can contact us," she says.

Inova developed an informed consent template specific to its central IRBs, which approved this language as part of the contract process, Ababio says.

"We gave them the exact template for the informed consent," she explains. "We have wording that is very specific for each section, and they approved the language before ratifying our contract and they were OK using this language."

Study teams insert the approved language into the sponsor's consent form when they submit the consent document to the IRB of record.

"They may negotiate with the sponsor to make sure they understand this is language that needs to be required, and most sponsors are fine with it," Ababio says.

• **Check for consent errors.** The IRB reviews the informed consent form post-approval by the IRB of record, Ababio says.

"We see if our language was used as required by the contract, and if there's a problem we have someone on the study team rectify the problem," she says. "That process has reduced the number of errors from what we found prior to reviewing it post-approval."

For example, the IRB once found that the IRB of record had reverted to the informed consent that had the sponsor's language. "We reminded them that this language must be present, and they'd go back and fix it," Ababio says.

Collecting errors data also helped one central IRB make quality improvements.

"The IRB was interested in knowing how many errors were made because they pride themselves on following the contract," she says. "We checked and told them the errors we had found, and since then they've been very cognizant to ensure they follow the contract and template language."

As a result, the number of errors has decreased tremendously, Ababio says. The reduction in errors was one of the positive changes to the program.

"We've looked at our process and streamlined it so we could have improved metrics with a turnaround time and reduction in errors in the post-approval process," Ababio says. ■

REFERENCE

1. Kim C, Pulsipher E. Cultivating a successful partnership between institutions and central IRBs. Poster presented at PRIM&R's 2016 Advancing Ethical Research Conference, held Nov. 13-16, 2016, in Anaheim, CA. Poster: 39.