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To Build Trust, HRPPS Should 'Look In The Mirror, Not Out The Window'

By Theresa Defino

Members of institutional review boards (IRBs) and others who oversee human research protection programs (HRPPs) have a variety of training options available to them. But has there ever been a course or conference offering titled, "How to deal with a difficult HRPP?"

That's a question that occurred to John Baumann, Indiana University (IU) associate vice president for research compliance, who recounted that, in contrast, he has seen plenty of speakers addressing how to handle "difficult researchers."

Speaking during a session on building trust between IRBs and researchers at the recent annual meeting of Public Responsibility in Medicine and Research (PRIM&R),[1] Baumann noted that he still thinks like a sociologist "even though it's been a very long time since I've practiced sociology." As such, he described strategies to cultivate trust based on a framework anchored by authority and legitimacy.

Of the types of authority sociologists say exist, Baumann told the PRIM&R audience that HRPPs can base theirs on the rational authority model, "which is built on a system of rules and processes that are implemented with concern with consistency and transparency. The goal of the HRPP is really to be seen as a legitimate authority."

Understand Causes of Inconsistencies

According to Baumann, reaching this goal requires that IRBs and HRPPs embrace four "building blocks." Two are operating with transparency and with consistency.

He said that one key to transparency, "especially when we're dealing with researchers and faculty," is to understand "the value of providing a rationale for our actions." Investigators "want and need that," Baumann said. Providing a rationale "would also provide an educational value" and could "impact subsequent submissions by this investigator." Acknowledging that this "admittedly does require a bit more effort by the reviewer," Baumann said the extra work is "not that substantial. And the follow-up benefit is substantial."

When it comes to consistency, this is an imperative for staff, reviewers and committee members. "Lack of consistency is a killer," said Baumann. "Few things irritate a researcher more than the perception that we're being inconsistent in our review. Now, admittedly, we all have situations in which what the researcher thinks is an inconsistency is not really an inconsistency because there are two different situations," different factors, or "different sets of relationships or research processes."

Yet, it is important to admit when this isn't the case.

"Sometimes we truly are inconsistent," Baumann said, "and we need to fess up to it when we are, and we need to approach and try to deal with it. We can seriously undermine the legitimacy of an HRPP when gross inconsistencies occur." When they do occur, the HRPP needs to explain if it is "legitimately" being inconsistent or, if it is not, address an inappropriate inconsistency.

One response to inconsistency, perceived or real, may be for investigators to "try to time their submission in order to avoid one of our committees," Baumann said. "We have had situations, I'm sure all of you have had, in which a researcher says, 'This exact same protocol,' or, 'This exact same design, this exact same activity, was approved last time.'"

Emphasizing and enhancing consistency require an acknowledgement that this is an ongoing challenge, because regulations "don't tell us what to do…they give us guidelines, and then we have to implement those," Baumann said. IU has a "strong program of education and guidance regarding the institutional approach to the implementation of those regulations," he added, noting that different institutions "interpret the same regulation somewhat differently."

The tolerance for risk will vary, and education and guidance are necessary to ensure the "level of comfort with risk, our way that we're implementing the regulations, [is] clear to all parts of the HRPP," Baumann said. Institutions, for their part, also must "monitor the HRPP determinations and follow up as necessary to make sure that your…staff members are more or less operating in the same way, that there are not any individual or idiosyncratic variations between how each of them review something and how each of them define and perceive something."