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Investigator attendance at review board reviews: hindrance or help?

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Inviting researchers to attend institutional review board sessions designed to approve these same investigators' requests to conduct research involving human subjects doesn't seem to affect the efficiency of the process one way or the other, a new study led by Johns Hopkins bioethicists suggests.

The findings are the result of one of the few studies to date that have sought to verify or challenge a fairly wide perception that inviting participation by so-called principal investigators, or PIs, could introduce more inefficiencies in what already is a lengthy and detailed process beset by scheduling problems, poor investigator-IRB relationships and administrative delays. Some researchers have suggested an opposing view: that inviting PIs can improve efficiency.

"The limited data on IRBs indicate they do not routinely invite PIs to attend convened meetings," says Holly Taylor, assistant professor in the Department of Health Policy and Management at the Johns Hopkins Bloomberg School of Public Health and assistant director of empirical research at the Johns Hopkins Berman Institute of Bioethics. She and her coauthors on the review of IRB practices at The Johns Hopkins University say one national estimate found that fewer than 9 percent of IRBs require PIs to attend the meetings.

Under federal law and regulations, and to assure the safety and welfare of research volunteers, all institutions that receive federal funds to conduct human subject research require review and approval by an IRB,

a group generally composed of senior scientists not involved in the research under review along with individuals who represent the lay community. Bioethicists and others familiar with human research protocols also may be involved.

Among other things, IRBs carefully consider questions such as whether the study's science is valid and generalizable, whether its benefits outweigh risks that volunteers might encounter, and whether volunteers will be adequately informed about the study to consent to participate.

While serving as members of four IRBs at the Johns Hopkins University School of Medicine, Holly A. Taylor, Nancy E. Kass and other bioethicists at theBerman Institute of Bioethics noticed that some IRBs regularly invite PIs when their research plans are discussed while other IRBs do not.

Wondering whether there was any difference in inefficiency between IRBs that did or did not invite PIs, Taylor and Kass, along with former Johns Hopkins master's degree student Peter Currie, now a law student at Georgetown University, looked back at 125 IRB reviews conducted by four Johns Hopkins School of Medicine IRBs between March 2002 and June 2005. Two of the IRBs did not regularly invite PIs to their meetings, one did, and a fourth switched midway through the examination period from not inviting PIs to inviting them.

The team wondered, for example, whether PIs in attendance could more efficiently answer any questions that arise quickly and directly, rather than by replying to multiple calls and e-mails from different board members after a meeting takes place. So they checked the total time it took to approve the research plans, how many pieces of correspondence passed between the IRB and the PI, and how many meetings took place where a particular study was discussed.

Their analysis, published in the January-February Issue of IRB: Ethics & Human Research, showed few differences between IRBs that invited PIs to attend meetings and those that didn't. All took an average of 65 days to approve each study's plans, had about five pieces of correspondence pass between the IRB and the PI, and reviewed a study at an average of 1.6 meetings.

Taylor noted that in the IRB that switched from not inviting PIs to inviting them, time to approval went down from an average of 114 days when PIs weren't present at meetings to 70 days when PIs attended. Additionally, the number of meetings where each study was discussed changed from an average of 2.4 to 1.7. The researchers aren't sure whether the presence of the investigator was a factor in this improved efficiency, but they suggest that it could be one of many factors that led to the change.

"PIs are really busy, and some IRB members might worry that requiring PI attendance could delay scheduling. We didn't find that was the case," she says.

She and her colleagues plan to eventually test PI attendance at multiple research institutions prospectively by randomly assigning PIs to be present or absent at meetings. Taylor notes that finding ways to improve the efficiency of IRB approval can help researchers begin their research faster.

Source: Johns Hopkins Medical Institutions