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# On Site: Parker Institute's IRB Reliance Agreement Signals a New Phase In The Trend Toward Consolidation

The Parker Institute for Cancer Immunotherapy, a coalition of six centers focused on cancer immunotherapy, has announced a streamlined process dubbed the Institution Review Board (IRB) Reliance Agreement.

The IRB Reliance Agreement is the most recent development in a growing movement to consolidate IRBs at academic centers. The concept was pioneered by the University of California system in 2006 and later replicated by Harvard-affiliated hospitals. Eight research centers in Ohio adopted a similar reliance agreement and an online submissions system, a process that shortened approval timelines from an average of 25 days to only eight.

While not unprecedented, the Parker Institute's model is unique in that it consolidates the IRB process in major academic research centers located in different parts of the country, according to Shirley Dang, science communications manager, Parker Institute for Cancer Immunotherapy. Its members include Memorial Sloan-Kettering Cancer Center, Stanford Medicine, UCLA, UCSF, the University of Pennsylvania, and The University of Texas MD Anderson Cancer Center. The Institute is also working on similar agreements for the scientific review committee process, Dang said.

Typically in an academic research study, every site's IRB would review a trial protocol, and any changes would need to be reviewed and approved by each IRB. The Parker Institute anticipates that its IRB Reliance Agreement will save "significant time and resources, and ideally get effective immunotherapy treatments to patients more quickly," shortening the IRB timeline from months to weeks, Dang said.

Ramy Ibrahim, M.D., vice president of clinical development at the Parker Institute for Immunotherapy, said, "With this agreement in place, a participating site would rely on the review that already took place at the IRB of record and potentially obtain approval in a matter of weeks. For example, Institution A wants to open a multicenter trial. Institution A (the Lead site) submits to their IRB. In three months that trial is IRB-approved. Institution B wants to participate, so instead of submitting to their own IRB and waiting another three to four months to obtain approval, they use the reliance agreement. Institution B submits to Institution A's IRB — the IRB of Record; the IRB of Record reviews Institution B's application and approves the site to conduct the trial. In this way, it is possible that approval could be received in a few weeks, rather than in three to four months."

There are over 3,000 IRBs in the U.S., and many of them are large central IRBs, said Scott Ballinger, founder of the Trial Acceleration Institute. Feeling pressure from highly competitive central IRBs, it makes sense that a growing number of academic research centers are looking for ways to safely accelerate the research process, Ballinger explained. Consolidating to one overarching IRB can trim the review process from four months to four weeks, which is "a big time and cost savings" that could help single IRBs better compete with central IRBs, Ballinger said.

With respect to the Parker Institute IRB, "six organizations are going to be collapsed into one process, and that alone will have an impact on the timeline, and by agreeing on a common set of language across institutions, the iteration process will also shrink," said Ballinger. Eventually, "these types of efficiencies are going to be required of the larger research institutions to stay competitive with increasing cost and time pressures," Ballinger said.

"We are unique in that we are working closely with the IRBs and the research programs to develop SOPs and standardize workflow," said Ibrahim. "We are sharing information and resources across the institutions, and eliminating redundancies that often slow down the submission process at the research program level and the review process at the IRB level."

The concept of a single IRB, which the Parker Institute is calling its reliance agreement, is a movement that is percolating elsewhere in the U.S. as well, Ballinger continued.

"Here in Philadelphia, home to many leading research centers, similar plans are being discussed, and the driver is in fear of losing out on future programs due to perceived inefficiencies in these same processes," he said.

This trend may be fueled in part by a push from the NIH, which earlier this year announced a new policy that states a clear preference for single IRBs. The policy, which will be finalized in May 2017, will cover all domestic, multisite studies funded by the NIH.

One of the central challenges in adopting a single-IRB model will be determining which center to appoint as the designated IRB of Record, said Ballinger. Challenges will likely boil down to the nuances of the language of each agreement, with each center striving to ensure that it has an equal voice in the consolidated processes and to ensure its interests are represented, said Ballinger.

The Parker Institute is focused on solutions around cancer immunotherapy, but the concept of a single IRB has applications far beyond oncology. The first such agreements, pioneered at the University of California system, originally covered only low-risk studies, and later expanded to include riskier research testing experimental therapies in patients.

The Harvard-affiliated IRB agreement was forged in the wake of the Boston Marathon bombing in 2013, when many victims were afflicted by blast-related ear injuries typically seen in combat. A single IRB was set up quickly as an effort to study the best treatment approaches and prepare for potential future tragedies. As single IRBs become an increasingly common trend, cancer trials and other life-threatening therapeutic areas are a good place to start. The IRB review process is the same across almost all therapeutic areas, and the pharmaceutical industry is interested in collapsing timelines across the board, Ballinger said. Therefore, institutions contemplating a shift to single IRBs should prioritize from the patient's point of view. In cancer trials and other grave therapeutic areas, condensed timelines become even more important for patients, he continued.

Ibrahim said, "This approach could be applied more broadly and shouldn't be limited to cancer immunotherapy. It is a refinement and streamlining of the process and introduces a paradigm shift. If we want to advance the science and bring better therapies to patients, we can't just continue with a business-as-usual approach."

"It has long been a struggle for the industry to get through these processes in an efficient way," Ballinger said, and single IRBs can safely eliminate redundancy and eliminate several cycles of iteration.

"I think everyone recognizes that resources can be scarce," said Ibrahim. "Academic IRBs may lack the funding, staffing and other resources to review, approve and monitor in a timely manner the numerous trials their faculty would like to conduct. Consolidation allows for shared resources across a network of sites. IRBs are recognizing some of their limitations. They want to maximize efficiencies and reduce some of their burdens. Reliance agreements are one way to accomplish that, as they remove duplicative efforts that happen during the review of a clinical trial."

*— Sony Salzman*

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