An IRB Ahead of the Curve

Virtual, fast, efficient.

That's how, Gil Price, MD, Institutional Official, MaGil IRB describes his company's approach to reviewing protocols for Pfizer, Merck, AstraZeneca, other big players, and a variety of CROs and small biotechs.

"Utilizing cyber-credentials based on the SAFE-BioPharma standard allowed us to create a fully electronic, virtual IRB," he explains. MaGil has created a new model for the traditional IRB. Being electronic allows it to respond to client needs faster and more efficiently.

Sponsor protocols awaiting review are sent electronically and simultaneously to each member of the MaGil review panel, where, within four hours, each person confirms receipt and has checked the protocol for significant issues. Expedited protocols are turned around in a few days. Full reviews are completed in a week. Documents are signed using SAFE-BioPharma digital signatures.

"It's a better mousetrap," Dr. Price says. "There are more than 900 IRBs in the US and the vast majority are still wedded to paper and the costs and delays associated with paper." He cites three primary reasons for abandoning paper.

1. Shipping — Courier services are costly and time-consuming. Sponsors save by sending and receiving documents electronically.

2. Signing — Signatures are applied digitally. With each signature is an automatic time-stamp and full assurance that any subsequent document change is visually evident with an invalidated signature. "Using the mobile version of SAFE-BioPharma lets our review board review and sign, wherever they are. Waiting to return to the office from a trip is no longer necessary."

3. Storing — While not yet a thing of the past, file cabinets no longer take up space. All records are stored and accessed electronically.

The company was recently accredited through the Association for the Accreditation of Human Research Protection Programs (AAHRPP) and completed a successful routine audit by the US Food and Drug Administration (FDA) audit.

Other virtual components are twice weekly teleconference meetings of MaGil's review board. Meeting notes are taken and distributed electronically. And researchers are able to sign and send submissions via computer or any mobile device.

Some MaGil clients continue to rely on the paper model, but Dr. Price and his colleagues are encouraging them to change. "It's hard to break from a paper-based culture. But the advantages are overwhelmingly in favor of making that change," he says. "The advantages for us and for the clients using SAFE-BioPharma are immediately evident. My colleagues and I live it daily. It's a matter of time before the rest of the IRB community and the life sciences read the memo."