

Human Research Relies on Accuracy, Honesty, Attention to Details, and Quick and Effective Response of the IRB

Ethical Integrity of Independent IRBs

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Being in the IRB industry for more than 20 years, I attest that all independent IRBs are not representative of the particular IRB that was the recent target of the U.S. Government Accountability Office (GAO) sting.

It is very disheartening to hear a client tell us that an institutional IRB staff member stated that he did not trust independent IRBs since learning about the GAO sting. Ethical integrity has been proven by the fact that two other independent IRBs refused to approve the bogus study. To use a popular quote, "One bad apple does not spoil the bushel."

Common Goals and Integrity

Independent IRBs do not wish to be competitive with institutional IRBs. Rather, we respect the role of the institutional review board and prefer to partner with them to achieve our common goal of adequate protection of human study participants. Given the opportunity, this partnership could be very beneficial to both parties.

Independent IRBs fulfill a niche in the industry that allows researchers who are unassociated with an institution the ability to be involved in the conduct of clinical research. Who would review their research if independent IRBs did not exist?

Quality and integrity are essential to the services IntegReview provides. Human research is a field that relies on accuracy, honesty, individualized attention to details, and the ability to respond quickly and effectively in a rapidly changing professional landscape.

Our key relationships with customers are based on and driven by our Core Values, Mission, and Vision Statement. Our board members and employees continually maintain high standards of quality, ethical integrity, and regard for human safety while being responsive to customer demands and needs for prompt, thorough, and professional services.

Employees work in a fast-paced, highly responsive, open, and adaptive culture that is reflected in the company's mission, which states it will "Provide unsurpassed ethical review services while acting as an advocate for research study participants." Furthermore, we have committed to a 24- to 48-hour turnaround time, in addition to complying with federal regulations, utilizing quality control process, employing the latest technologies, and being flexible to customer needs.

Flexibility and Turnaround Times

Some have voiced concerns with the ability of an IRB to provide turnaround of study documents within 48 hours of board review. However, independent IRBs are businesses and, as such, must be cognizant of client expectations. As an independent entity, we are able to provide necessary resources as they are needed to ensure we continue to meet the expectations of our clients. The 48-hour turnaround time was a key policy and business practice improvement implemented by IntegReview in response to requests from our customers and to the changing environment in the human research field. Customers and clients re-

requested the flexibility to forward requests for approval of research with a shorter lead time, but still receive the high standards of scientific review, attention to detail, and responsiveness.

In response to these requests, IntegReview developed strategies and procedures to facilitate quality, thorough review with a rapid-turnaround process that our customers now rely on. To accomplish this, we trained staff as well as our group of consultants in guidelines and deadline goals for rapid-turnaround submissions. Since all materials for each research study are processed in multiple stages by various staff teams, this required us to analyze the flow of documents and materials at all levels. Once this was done, staff and consultants were trained in specific ways to process rapid-response requests in order to assure that quality standards are maintained at the same time flexibility and timeliness are addressed.

In 2005, IntegReview implemented a Corrective and Preventative Action (CAPA) program. This program identifies errors discovered internally versus those discovered by the client. It also assists in identifying the root cause that can result in process improvements. IntegReview's staff and consulting committee members routinely handle approximately 3,100 documents per quarter, with an average accuracy rate of between 98% and 99%. Errors that might have been prevented through improving internal processes are used as learning opportunities for either staff training or for adopting new steps in processing or changes in quality checklists.

Among IntegReview's successes in using the CAPA program to ensure high-quality customer service has been its regular examination and improvement of its checklist and review process.

Another area of importance is continuous training. At least annually, customer service training is provided to all staff.

In 2008 we conducted a training session regarding how our core values impact everyday interactions, a series of workshops based on *The 7 Habits of Highly Effective People*, and training sessions on professional communication as well as conflict resolution.

At a recent conference where we were exhibitors, many attendees posed the same questions: "Would your IRB

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have discovered a bogus study and how would you detect this?"

Given the detail of quality assurance performed by our Quality Assurance Department, we feel comfortable that we would not fall victim to a similar situation.

The numerous checks and balances employed by our Quality Assurance Department would not allow the clinical study to be assigned to any of our boards for review. As part of our quality assurance process, extensive checklists are utilized that would allow us to identify potential issues of concern.

Ethical integrity can be demonstrated in a number of ways. I believe that independent IRBs are very dedicated, committed, and focused on ensuring compliant behavior and play an increasingly important role in providing adequate protection of human study participants.

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