

IRBWISE™: Web-Based Software for the Institutional Review Board
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Abstract

IRBWISE™ is an online, web-based tool for use by human subjects researchers and Institutional Review Boards. Organizations that conduct human subjects research are required by federal law to have their research reviewed and approved by a board of experts in protecting human subjects, known as an Institutional Review Board. Georgia Tech Research Institute, the applied research arm of Georgia Institute of Technology, has developed IRBWISE™ for use at Georgia Tech to help make this process more efficient and more effective.

Organization

The Georgia Institute of Technology is one of the nation's top research universities, distinguished by its commitment to improving the human condition through advanced science and technology. Georgia Tech's campus occupies 330 acres in the heart of the city of Atlanta, where more than 15,000 undergraduate and graduate students receive a focused, technologically based education.

Georgia Tech Research Institute (GTRI) is the nonprofit applied research arm of the Georgia Institute of Technology. GTRI's approximately 1,200 employees perform or support more than \$100 million in research yearly for more than 200 customers/sponsors in industry and government.

GTRI's Information Technology Department supports the Research Institute's business, financial, project management, and research needs. Its areas of expertise include hardware support, software development, web development, and database and systems support.

Georgia Tech's Institutional Review Board (IRB) is charged with ensuring that the rights and welfare of human subjects are protected by reviewing projects and activities at Georgia Tech that involve human subjects. The IRB has the responsibility

and authority to review, approve, disapprove, or require changes in research activities involving human subjects.

Problem

The requirements for human subjects protection set forth by the Office of Human Research Protections (OHRP) make it challenging for the IRB to effectively and efficiently perform its duties through a purely paper-based workflow process. The IRB is required to keep a full record of each research activity (protocol), including any changes or renewals requested, or adverse events (such as a death or hospitalization of a subject). They are also required to keep detailed minutes for all board meetings, a record of communications between the board and researchers, and detailed records of any actions that the board takes.

At the forefront of the review process are the IRB Administrators in Georgia Tech's Office of Research Compliance. The administrators are responsible for ensuring that protocols are reviewed in the proper manner, keeping records for the board, coordinating communication between the researchers and the board, and executing the decisions of the board. On a daily basis, the administrators may interact with dozens of protocols and researchers.

On the researcher side, many investigators view the board as a bottleneck to doing human subjects research. Georgia Tech continually works to dispel this view, striving to educate the researchers as to the need for careful review of their research by an independent board to ensure protection of human subjects. Additionally, the Institute benefits as a whole when its researchers not only understand the need for the IRB, but also are able to have their research be approved in a timely manner. Since many funding

sponsors require researchers to have IRB approval before competing for funding, an efficient system potentially results in a higher level of sponsored research income.

IRBWISE™ is Georgia Tech's solution to these issues. The goals of the software are to enable research to be easily submitted by the researcher to the IRB, to aid the IRB in reviewing the research in a timely and thorough manner, and to accurately record the auditable details of IRB activities. While IRBWISE™ was originally developed for Georgia Tech, it grew into a solution that is now commercially available to other institutions that do human subjects research.

Design

To design and develop this system, the IRB looked to GTRI's Information Technology Department (ITD). ITD has extensive experience in building such systems, having created an intranet for GTRI's Business Information that is also widely used on the academic side of Georgia Tech.

The first step in the design was to create a focus group of experts on both sides who would determine the requirements of the system. This focus group combined the human subjects protection expertise of the IRB with the technology expertise of ITD. At an early stage, Georgia Tech recognized the applicability of this solution to other institutions, and approached Emory University to request their involvement in the project. Over a period of about three months, the focus group members from Georgia Tech and Emory met, discussed the issues, debated potential solutions, and helped the ITD analysts develop rudimentary prototypes of the system. The analysts then presented the

prototypes to the focus group for their suggestions for improvement and for their acceptance.

The main issues discussed in the focus group meetings concerned what data needed to be captured in the system, who needed access to the system and what permissions they would have, how users would navigate through the system, and what the boundaries of the requirements would be. Having another institution involved in the design forced both institutions to evaluate their own IRB review processes and appeal to OHRP regulations for guidance in designing the system. Therefore, the designing of the electronic system by the focus group also benefited the IRB review process *outside* of the electronic system.

The focus group also decided that the system would be completely web-based. This decision was made to allow anyone with an IRBWISE account to access the system from any location in the world with an internet connection and web browser. Because investigators often use multiple computers in different locations, having a web-based system also reduces the amount of support required from ITD, since users are not required to install, maintain, and update any additional software.

Once the requirements and prototypes were developed and accepted by the focus group, the project manager added architects and developers to the team, and they began to create design documents to detail the underlying technology and algorithms that would be used to build the system. From experience on previous projects, the developers decided that the system would greatly benefit from standard naming rules, standard methods for accessing data, and a common library of existing software code. These

conventions proved to be very important during the development phase by saving time and reducing coding errors.

Implementation

The implementation process was initially planned for four months. However, the developers quickly realized that the requirements set forth by the focus group were quickly growing and changing. During the design phase, the analysts had become somewhat familiar with the IRB process, its terminology, its workflow, and its data requirements. As the implementation began, the developers spent a great deal of time discussing additional issues that had not surfaced during the design phase. Some of these issues resulted from short-term thinking on the part of the focus group. Others were improvements in navigation and user interaction proposed by the developers.

Much of the existing manual process of the IRB had been written down during the design phase, but turning this into an electronic system meant having to know all the details of the process that were often second-nature for the IRB. As these issues surfaced, the development team had a critical question to answer: how much should the system control for the end-user, and how much should it allow the end-user to control? This philosophical question determined what kind of system would be built and what kind of experience the end-users would have. In the end, the decision was made to focus the system on data collection and automation, while allowing the end-user to control workflow and navigation (within limits).

Other issues arose because of a need to define key strategies for the areas with which the developers were not experts. The developers had to address the technology

supporting the detailed history and audit requirements, the different access levels required because of potential conflicts of interest, and many other issues not considered during the design phase.

Because of these issues and changes, the implementation process stretched out into roughly six months. Once the initial product was released, however, there was a general demand for it from other institutions. To date, IRBWISE™ has been licensed to or the license is pending for several research institutions across the country. Each new institution has its own “wish list” of features, so the implementation phase is even continuing into the present time.

Benefits

Since IRBWISE™ was first released to Georgia Tech in February 2002, it has had a significant impact on the human subjects research community. One of the most notable differences it has made is the raised awareness for the need to adequately protect human subjects. Because the IRB had to advertise to the campus that a new electronic system was in place and would soon be mandatory, researchers took the opportunity to learn more about the regulations and ensure that they would be able to continue their research under the new system.

IRBWISE™ has also greatly benefited the Georgia Tech IRB and Office of Research Compliance (ORC – the administrators and staff related to the IRB). Before the system was in place, the IRB and ORC spent a majority of their time on repetitive tasks such as standard e-mail and letter correspondence, organizing and sorting through filing cabinets for information, creating meeting agendas and minutes, and manually generating

reports for management and department heads. All of these tasks are now handled within the software and require minimal or no interaction from the IRB and administrators.

The IRB also can be more confident that necessary actions are taking place at the right time, like automatic expiration of protocols and generation of warning messages to investigators of protocol expiration. The paper that was previously stored in filing cabinets and manually sorted and retrieved is now accessible to the appropriate people in a few mouse clicks, without having to interrupt anyone else.

There are other cost savings and benefits that will be realized over the long term as well. Before IRBWISE™, administrators copied and distributed protocols for review, along with any supporting documents such as consent forms, relevant regulations, and survey instruments. The vast majority of this paper was discarded after the board meetings. Now, reviewers are able to access the same information in electronic format, with the option to print it if they desire. Not only does this save time and money, but it also benefits the environment by reducing the need for paper and landfill space.

Researchers have benefited from the system as well. It is an interactive program that helps them submit their applications by giving them hints, online help, and directed navigation. Because they receive automatic e-mail notifications that the system customizes for them, they know to wait for communication from the system instead of contacting the IRB directly. They are also able to log in to their account on IRBWISE™ and check the status and action history for their protocols. The IRB has noticed a marked decrease in the amount of time it spends corresponding with the researchers over these issues.

All of these benefits have made such an impact on all users who interact with the system that Georgia Tech is considering expanding this system into its bio-safety and animal research arenas.

Retrospect

The IRB and developers learned several lessons from this experience that have translated into improvements in this product as well as improvements in new products developed by the Information Technology Department. Had the developers realized the level of outside interest that there would be in the product, they would have made it even more flexible and customizable than it already is. The new rule with improvements is to anticipate changes before they are requested and build with them in mind.

Another key change would be to include more end-users in the focus group, particularly researchers. Since researchers do not use the system as often as the IRB or administrators, it would have been helpful early on to understand their needs better rather than have to make changes after the system was developed. The focus group also needed time to codify their own business rules that were both unwritten and also changing to adapt to changing federal requirements. These rules could have been worked out before the design of the system rather than having to delay the design to express the business rules.

Despite these oversights, the system has been an overwhelming success. It has been a model for competing products and for other institutions building their own systems. Georgia Tech is proud to have developed IRBWISETM, and continues to improve and expand the software.