

Wake Forest University Health Sciences IRB Goes 'Beyond Paperless'

Proven eIRB Enables New Breakthrough in Collaboration among Researchers



Wake Forest University Health Sciences, a leading academic medical center and research institution

Research Profile

Clinical, behavioral, and public health studies as well as biomedical engineering

Business Challenges

- Expensive, cumbersome and unreliable paper-based IRB processes
- Growing and increasingly dispersed user population

Solution

Click Commerce eResearch Portal for Institutional Review Board (IRB)

Results

- Enables creation of a new system that promotes productive collaboration among researchers with similar interests
- Saves 5.7 tons of paper annually
- Saves \$50,000 a year in printing costs
- Saves 15 work weeks a year in copy time
- Frees up storage space for other uses
- Shortens turnaround times
- Improves productivity
- Increases accuracy

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Scott Mann

*eIRB Lead Developer
Wake Forest University Health Sciences*

Wake Forest University Health Sciences (WFUHS), located in Winston-Salem, North Carolina, is one of the nation's leading academic medical centers and research institutions, supporting basic science and clinical research, and funded by about \$190 million a year in total outside research support.

Together with Wake Forest University, WFUHS co-manages the Wake Forest University School of Medicine, whose 880 full-time faculty members guide 120 students a year through nationally recognized MD, Ph.D. and joint-degree programs. Wake Forest University Baptist Medical Center has received Hospitals & Health Networks magazine's "Most Wired Hospital" designation five times. In 2007 it was one of only two hospitals in North Carolina and 100 in the nation to receive this distinction for the advanced use of information technology in safety and quality, customer service, business process, workforce, and public health and safety.

WFUHS is currently leading the development of the Piedmont Triad Research Park expansion project in Winston-Salem, which is reclaiming more than 200 acres of the downtown area for research and other mixed uses over the next 20-30 years.

Wake Forest University Health Sciences investigators are currently involved in more than 2,000 active human subjects research protocols encompassing a wide range of clinical, behavioral, and public health sciences and biomedical engineering.

Business Challenge

In conducting state-of-the-art medical research, WFUHS combines the use of leading edge technology with a strong commitment to ethics and safety. With the volume of research continually growing and paper-based processes becoming increasingly cumbersome and vulnerable to error, WFUHS embarked on an ambitious effort to streamline and strengthen its Institutional Review Board (IRB) processes and further ensure patient safety.

"Our enterprise was expanding, with departments and clinics moving to other locations throughout the city," said Cheryl Byers, WFUHS IRB director. "We needed an IRB administration system that would make physical location irrelevant and also allow us to

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Cheryl Byers
IRB Director
Wake Forest University
Health Sciences

consolidate a large variety of forms and ancillary committee review requirements into a single guided workflow process.”

In essence, WFUHS needed to find an automation solution partner whose system would reduce and ultimately eliminate paper consumption; provide complete transparency of study progress; create a repository of searchable information; provide templates to minimize time spent on administrative processes such as building agendas, minutes, and approval letters; and enhance security through audit trails with time-stamped activities.

Solution

The search ultimately led WFUHS to the selection of Click Commerce Research and Healthcare. Click’s eResearch Portal for IRB proved to be the only automated solution that allowed Wake Forest Health Sciences to configure the system according to its own workflow forms and processes while also meeting the institution’s collaboration and security requirements.

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Director Byers also cited as critical Click’s fully web-based system, which meant no software for WFUHS researchers to install and maintain, as well as the eResearch Portal being intuitive enough for IRB staff to use it easily with minimal training.

After a successful pilot release in October 2005, the new system became mandatory for all new submissions beginning in February 2006. During 2006 and 2007 all legacy paper studies were converted into electronic format.

While WFUHS had been using eIRB’s electronic meeting management functionality since 2005, fall 2007 brought a significant landmark, the IRB’s first agenda composed entirely of electronic submissions. By January 2008, the conversion effort was complete, and WFUHS had reached its goal of a fully paperless IRB.

Results

eIRB has been welcomed by members of the WFUHS research community, who have experienced the wide range of benefits of a fully electronic IRB process. Scott Rhodes, Ph.D., Associate Professor in the WFUHS Division of Public Health Sciences, has seen the transformational impact of eIRB as a researcher and frequent user of the system. “eIRB is a tremendous improvement over paper submissions because it is efficient and very fast. Errors can be corrected quickly, and the study can get approved and initiated much faster,” noted Dr. Rhodes.

He added, “Another advantage is that all study related materials are saved in one place, making the grant document, application, forms, advertisements, questionnaires, and amendments easily accessible. When copies of an approved consent form are needed, I can just go to the study workspace and print them. When a study approval is terminating, the system alerts the study team with renewal reminders. It’s such an efficient and user friendly system; it really walks you through the process.”

The savings in time and money are considerable as well: eIRB will save an estimated 5.7 tons of paper annually, \$50,000 a year in printing costs and 15 work weeks a year in copy time. Storage space once given over to paper is now being adapted to more productive use.

With paperless routing, full IRB turnaround times have shrunk dramatically, reaching a median of just 21 days for the months between May and December 2007. Protocol analysts send electronic notifications of concerns and often receive responses in a matter of hours rather than days, eliminating the communication lag inherent to paper-based processing.

“The savings in money—and especially time—together with the shortest imaginable learning curve meant we realized a very speedy return on our investment,” said Director Byers. “Moreover, IRB staff can now apply their energies to advancing research, not pushing paper. Qualified administrative assistants who no longer have to process memos and other paperwork have been able to undertake retraining and upgrade their positions to IRB protocol analysts who focus on such matters as the completeness of the application, the appropriateness of the answers, and the content of the informed consent and protocol documents. Their efforts in turn allow board members to concentrate on the science and ethics of the research.”

Paperless—Now What?

Even before going fully paperless, eIRB users began to realize that they had a system that could be leveraged to achieve benefits unforeseen during the original planning and implementation.

“It soon became clear that implementing an electronic active study base opened the door to possibilities that were unthinkable just a few years ago,” observed Scott Mann, lead developer for eIRB at WFUHS.

“Like other medical research institutions, we have been challenged by our faculty to provide new pathways for collaboration,” he continued. “We looked at several strategies and decided that we wanted to give researchers the ability to perform deep, meaningful searches into research studies that are happening right now at WFUHS. We also wanted to protect sensitive sponsor information, so we had the challenge of filtering access based on funding sources. eIRB collects hundreds of pieces of data for any given study, so all of these were available for export and reporting. Even better, the data was already being entered by the research teams and reviewed by the IRB, so harvesting data from eIRB meant that no administrative data entry would be necessary.”

Realizing the collaborative possibilities enabled by eIRB, the WFUHS Office of Academic Computing began brainstorming with Click Commerce Professional Services on ways to leverage eIRB data for protocol search functionality. The result is the Institutional Research Interest System (IRIS), a new application designed to query IRB-approved projects in order to connect collaborators by research interest.

Because of the flexible nature of the eIRB platform, the new application was designed completely in house. The Click Commerce eIRB also enables IRIS to stay current: the IRIS database is refreshed automatically via integration with the eIRB database so that only approved, ongoing projects are searchable.

Launched in January 2008, IRIS is generating impressive web statistics, averaging 640 visitors per month. Recent statistics show that the average visitor has been spending over three minutes on the site, data points which indicate that IRIS is being used.

“We’re looking forward to tracking the new collaborations enabled by the new system,” said Director Byers. “It’s clear today that the creation of IRIS has further enhanced the already measurable value of the existing eIRB investment. Together eIRB and IRIS are empowering researchers to team up and speed delivery of new insights, therapies, and other treatment options.”

About Click Commerce Research and Healthcare

Click Commerce Research and Healthcare is a leading provider of automated research administration and compliance systems to many of the premier research institutions in North America, including Johns Hopkins University, Duke University and the University of Pittsburgh. Click’s eResearch Portal can be configured to accommodate institutions of all sizes and is backed by an experienced Professional Services organization and the financial stability of a Fortune 200 company.

Take the Next Step

Contact us to find out how eResearch Portal can be licensed and configured to support your institution’s processes.

Visit us online at: research.clickcommerce.com, or call 1-800-590-5400.