

## The Research Institute at Nationwide Children's Hospital Expands Compliance Platform

### Click Commerce's eResearch Portal Streamlines Accurate Financial Disclosures by Researchers



The Research Institute at Nationwide Children's Hospital, a leading pediatric research center

#### Research Profile

Basic molecular biology to applied, patient-oriented research

#### Business Challenges

- Time-consuming processes for disclosing sensitive financial and other data
- Growth in industry funded studies, increasing the risk of conflict of interest

#### Solution

Click Commerce eResearch Portal for Conflict of Interest (COI)

#### Results

- Reduces average financial disclosure turnaround time from one month to as little as two days
- Saves each PI 30 minutes per disclosure
- Eliminates duplicate efforts
- Streamlines delivery of disclosure plans to study sponsors while increasing confidentiality
- Enables instantaneous reporting on institution-wide disclosures
- Saves thousands of sheets of paper and thousands of dollars in copy costs and clerical time

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#### **Kathy Milem**

*Vice President of Business Services  
The Research Institute at Nationwide  
Children's Hospital*

The Research Institute at Nationwide Children's Hospital, located in Columbus, Ohio, is one of the fastest growing pediatric research centers in the U.S. More than 100 faculty scientists focus on discoveries to improve child health, ranging from basic molecular biology to applied, patient-oriented research.

Underpinning these efforts is a clear mission: to enhance the health of children by engaging in high quality, cutting-edge research according to the highest scientific and ethical standards.

With 13 multidisciplinary Centers of Emphasis, 100 principal investigators, and more than 900 active protocols, The Research Institute received nearly \$50 million in external funding in 2007. While more than half that amount came from the NIH, industry sponsored funding has also continued to grow in each of the last three years. Increased external funding also increases the burden to reduce exposure to financial or other relationships that could create a conflict of interest (COI) between researchers and sponsors.

#### Business Challenge

The Research Institute's growing volume of industry-funded research began to place stress on the financial disclosure process at least two years ago. Drafting detailed disclosures of sensitive financial information and submitting them for routing through inter-office mail packets created discomfort among researchers and staff alike: where researchers sought assurances for the safe handling of the information, administrators were growing frustrated at the time it was taking to locate and roll-up the information to identify potential conflicts. Tabulating responses and approvals from paper forms was slow, error-prone and required special filing to ensure confidentiality.

"Our approach is to require a financial disclosure with every grant application," said Kathy Milem, vice president of business services at The Research Institute. "Previously in each case, a form had to be completed, with additional different forms for human and animal studies. These were paper forms that had to be printed, filled out, signed, sent to legal for review, and then, in some instances, routed to the appropriate IRB committee. We were constantly

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chasing paper and inundating the legal department with forms, many of which had only a little information. I had an assistant who easily spent half her time tracking COI disclosures.

"But the frustration was acutest for our PIs," she added. "We have PIs that have up to 15 different grants, each one on a different award cycle. A PI in this circumstance might have to complete 15 different disclosure forms in the space of a few months, one for each grant as it renewed. With this steady flow of forms, a PI would often lose track of whether the form had been completed or not. Worse still, lost forms meant lost research time for our PIs as well as the anxiety caused by not knowing where their confidential information might be lurking. The situation was really becoming untenable."

In seeking to centralize and automate this fragmented approach to managing financial disclosures, The Research Institute looked for a solution that would help them reduce risk while streamlining their compliance efforts. They also wanted to eliminate redundancies by ensuring that every disclosure became part of a PI's profile while at the same time enabling new COI information to be easily entered, preserved, and applied as needed.

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## Solution

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As a long-time Click Commerce Research and Healthcare customer, The Research Institute surmised that Click's eResearch Portal COI solution would offer the scope and flexibility they required. The eResearch platform manages disclosure creation, submission, routing, review, monitoring, and reporting—all according to an institution's own processes and frequencies—while speeding decision making and improving accuracy.

"We have had great success with several Click Commerce eResearch Portal solutions," said Milem. "In fact, we were the very first Grants customer, the first IACUC customer, and the second IRB customer. So you might say we're more than just loyal customers: we're fans. We know their systems work—both on their own, with each other, and with our other business systems. We knew their COI solution would be compatible with our existing Grants, IRB and IACUC applications—critical for eliminating the redundancies in our processes. The eResearch Portal is so robust that it accommodates all these diverse research administration and compliance functions while allowing us to implement our own look and feel. This increases our researchers' satisfaction because the learning curve is very short."

During the implementation and integration phase, teams from The Research Institute and Click Commerce worked collaboratively to convert paper forms and processes into a centralized, automated workflow process.

"With any conversion of paper to electronic systems there are always small issues that crop up unforeseen," said Milem. "The beauty of the Click Commerce solution is that these are quickly identified and addressed. It's usually a matter of making some minor adjustments to the forms. The underlying technology is solid, allowing for changes and corrections as well as ongoing refinement of the application to meet new needs."

## Results

With a March 2007 project kick-off, full implementation commenced in July 2007. Since then, The Research Institute has seen dramatic improvements in both productivity and PI satisfaction.

"We've gone from taking up to a month for each disclosure to as little as two days," said Milem. "We're no longer chasing paper, disclosures are not lost, and we can track a particular form at any point in time. We also have one form that satisfies both our grant application and IRB/IACUC requirements so there's no duplication of effort. And we're saving thousands of sheets of paper and thousands of dollars in copy costs and clerical time. These are tremendous benefits.

"Now when a grant renews, with a couple of clicks of the mouse our PIs merely approve the information already provided or update the record online. They can easily track a disclosure's status if they need to, and they no longer have to worry that their confidential information will be misplaced or lost.

"We know we're now more compliant than ever," added Milem. "By that I mean that we can tell immediately if all the i's are dotted and the t's crossed, and if they're not, there's little time wasted in rerouting a document to solve the problem. This keeps investigators and reviewers alike focused on research, not paperwork."

## An Added Benefit

"One of the unforeseen benefits of the Click system has been the enablement of a new paperless conflict management plan to manage identified conflicts with sponsors," said Milem. "Because the existence of a conflict management plan has to be reported to many grant and contract sponsors, we need to ensure the plans are completed in a timely manner and monitored effectively. The new system has enabled the Compliance Office to complete conflict management plans and obtain the PI's approval much faster.

"I guess you could say the ultimate benefit is all around peace of mind—and the confidence that our research on behalf of children's health can go forward on a sound ethical basis."

For more information on The Research Institute visit [www.nationwidechildrens.org/research](http://www.nationwidechildrens.org/research).

### 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 Commerce'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](http://research.clickcommerce.com), or call **1-800-590-5400**.