

Transforming the Human Research Protection Program at Pennsylvania State University

“Huron’s guidance was key to our success. This has been a great relationship and has resulted in tremendous improvements for our researchers, staff and board members. CATS IRB is appreciated by those who use it regularly and feedback from the research community has been extremely positive. We look forward to continuing to partner on other projects.”

– Candice “Candy” Yekel

Associate Vice President for Research, Director, Office for Research Protections

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The Background

Pennsylvania State University (Penn State), is recognized as one of the as one of the country's leading research universities, boasting an \$805 million research program. With 24 campuses throughout Pennsylvania and a medical school located in Hershey, Penn State's research awards and expenditures have increased substantially over the past 10 years.

Penn State's Human Research Protection Program (HRPP) is supported by two offices: the Office for Research Protections (University Park) and the Human Subjects Protection Office (College of Medicine/Hershey Medical Center). Tasked with reviewing and overseeing approximately 7,000 submissions each year, Penn State's HRPP was seeking a replacement for their “homegrown” electronic Institutional Review Board (IRB) system, which was cumbersome, inefficient and frustrating to use for researchers, IRB staff and committee members. In addition, they recognized that there were opportunities to streamline current processes to improve research startup times, improve the researcher user experience with the IRB, restructure HRPP staffing and enhance communication and standardize procedures between the two HRPP offices.

Penn State engaged Huron to assist them with a complete IRB transformation. This included deploying a new electronic IRB system, Huron's Click® IRB software, as well as implementing Huron's HRPP Toolkit, a comprehensive set of workflows, standard operating procedures, checklists, worksheets and templates that meet regulatory requirements and standards for accreditation by the Association for the Accreditation of Human Research Protection Programs, Inc. (AAHRPP). Huron also provided support for the restructuring of the two HRPP offices and on-site mentoring for HRPP staff through the transformation. All of these initiatives led to a significant decrease in turnaround times, increased consistency in reviews and increased morale and satisfaction.



The Approach

Penn State and Huron were true partners during this IRB transformation. To lead the project, Penn State created an Advisory Committee that consisted of representatives from IT, both HRPP offices and HRPP leadership. Since the nature of this transformation was comprehensive across their HRPP program, it was approached in three phases.

Phase I – HRPP Business Process Changes

In order to provide a solid foundation for the implementation of the Click IRB software, Penn State implemented the HRPP Toolkit to focus on business-process changes. During this phase, Huron worked with Penn State to:

- Customize the HRPP Toolkit and incorporate Penn State-specific policies and requirements into the Toolkit
- Train IRB leadership, staff and board members on Penn State's new HRPP Toolkit SOPs, worksheets and checklists

- Implement IRB staff and member portions of the HRPP Toolkit while retiring existing policies and procedures
- Map out the new HRPP organizational infrastructure, draft and revise job descriptions, and create a transition plan
- Identify functional and technical requirements for Penn State's Click IRB system (named CATS IRB)

Phase I took approximately two months, with Huron providing a full-time on-site resource to assist with the HRPP Toolkit training and mentoring of IRB staff and members. In addition, Huron resources provided technical guidance to assist with the design of CATS IRB and to build a small number of customizations into the Click IRB product. One of the benefits of beginning with business-process change and conducting Huron-supported training of the HRPP Toolkit, was a better understanding of the Click IRB product, which resulted in Penn State staying fairly close to the delivered IRB system. This decision to stay as close to the delivered system as possible resulted in decreased implementation costs and time.

Phase II – IRB System Implementation and Training & Education

Phase II of Penn State's IRB Transformation focused on finalizing the building of CATS IRB, data migration from Penn State's legacy IRB system to CATS IRB and implementing the HRPP Toolkit researcher materials.

Throughout this phase, Huron provided support for the following tasks:

- Ongoing HRPP Toolkit mentoring with IRB staff and leadership
- Targeted quality assurance of IRB activities to assess adoption of the HRPP Toolkit
- Creation of additional protocol and informed consent templates
- Expansion of the Investigator Manual to provide detailed information regarding the use of CATS IRB
- Data migration of about 5,500 studies from Penn State's legacy system to CATS IRB
- Defining system requirements and enhancements
- CATS IRB development support
- Building a master data store for management of organization structure, sponsor, and person data, including training
- Integrating CATS IRB with the Clinical Trial Management System
- Development of a communication and transition/go-live plan for CATS IRB

Phase II took approximately 10 months and resulted in a successful go-live of CATS IRB: full go-live for the College of Medicine/Hershey Medical

Center and a tiered go-live for University Park. It took 12 months from the beginning of the project (starting with the HRPP Toolkit customization) to CATS IRB go-live.

Phase III – Post-Implementation Support

The final phase of Penn State's IRB Transformation focused on addressing any post go-live CATS IRB items and ensuring continued correct use of the HRPP Toolkit with CATS IRB. In addition, Penn State implemented the rest of the HRPP organizational infrastructure changes that Huron recommended in Phase I.

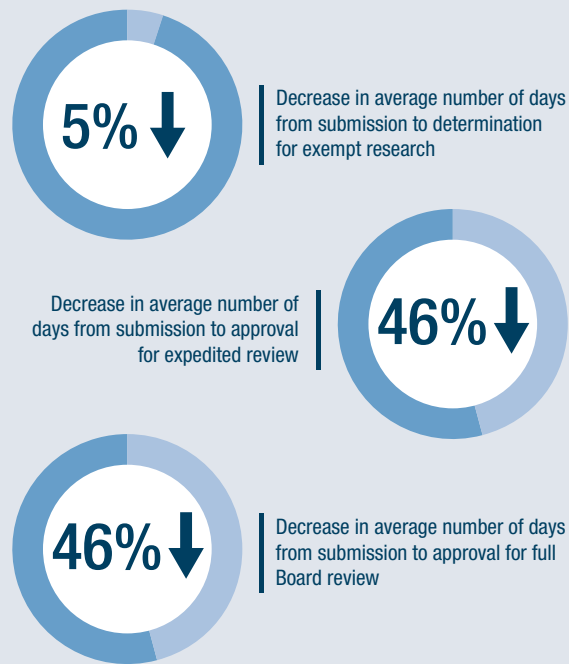
Specifically, Huron provided support for the following activities:

- Developed internal audit SOPs and tools for the use of the HRPP Toolkit
- Trained HRPP staff to conduct internal QA/audit of HRPP Toolkit use
- Provided AAHRPP application assistance, including compilation of the Step 1 and Step 2 applications
- Provided project technical support for three months post go-live (Huron continues to provide product support under the software maintenance agreement)

Huron provided support for five months after the go-live of CATS IRB.

Saving Time and Improving IRB Turnaround

As a result of this IRB Transformation, Penn State experienced the following:



The Results: Increasing Efficiency, Reducing Turnaround Times, and Improving Clarity

As a result of this IRB Transformation, Penn State experienced the following:

- Decreased IRB turnaround times
 - 5% decrease in average number of days from submission to determination for exempt research
 - 46% decrease in average number of days from submission to approval for expedited review
 - 46% decrease in average number of days from submission to approval for full Board review
- IRB submission-processing backlog clearance in approximately five weeks
- Decreased use of office supplies, especially paper and copiers
- Improved clarity in review process for IRB staff, IRB members and researchers
- Increased morale in IRB Offices and improved staff satisfaction
- Positive experience for researchers
- Enhanced consistency of reviews

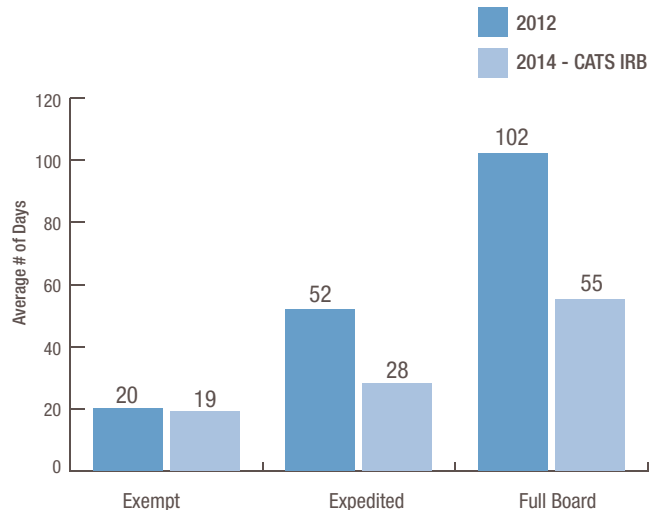
Penn State also applied for AAHRPP re-accreditation and had their site visit 11 months after CATS IRB go-live. There were no observations reported as a result of the site visit and therefore, a Site Visit Report did not even need to be issued.

In addition, the HRPP organizational infrastructure changes allowed Penn State to:

- Ensure that all IRB staff are trained on how to process all types of submissions
- Have staff fill in for each other with minimal cross-training
- Distribute workload evenly to help increase efficiency
- Appoint experienced and qualified IRB staff as IRB designated reviewers
- Create growth opportunities in an otherwise flat organization

Turnaround Times from Submission to Approval:

Then and Now



“I have heard uniformly positive responses from the faculty members at the College of Medicine since the implementation of the new CATS IRB system.”

Sheila L. Vrana, Ph.D., Interim Vice Dean for Research and Graduate Studies, Interim Associate Vice President for Health Sciences Research, Associate Dean for Research, Associate Professor of Pharmacology – Penn State College of Medicine

“We have considered Huron a part of our team in a very integrated and collaborative way. A lot of work and effort went into this IRB transformation project and we couldn’t have done it without all of your guidance and help along the way. Thank you!”

Jim Taylor, IT Project Manager, Office of Research Information Systems (ORIS)