

Transforming the Human Research Protection Program at Pennsylvania State University

Pennsylvania State University (Penn State) is recognized as one of the country's leading research universities, boasting an \$968 million research program. With 24 campuses throughout Pennsylvania, including a medical school, Penn State's research awards and expenditures have increased substantially over the past 10 years.

Challenge

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.

"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."

JIM TAYLOR, IT PROJECT MANAGER, OFFICE OF RESEARCH INFORMATION SYSTEMS (ORIS)

In addition, they recognized that there were opportunities to streamline current processes to improve research startup times, improve the researcher experience with the IRB, restructure HRPP staffing, and enhance communication and standardize procedures between the two HRPP offices.

Approach

Penn State engaged Huron to assist with a complete IRB transformation. This included deploying Huron's new electronic IRB system 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. These initiatives led to a significant decrease in turnaround times, improved consistency in reviews, and increased morale and satisfaction.

To lead the project, Penn State created an advisory committee that consisted of representatives from information technology (IT), both HRPP offices and HRPP leadership. Since the nature of this transformation was comprehensive, it was approached in three phases.

Phase I: HRPP Business Process Changes. In order to provide a solid foundation for the implementation of Huron IRB, Penn State implemented the HRPP toolkit to focus on business process changes.

Phase I took approximately two months, with Huron providing a full-time, on-site resource to assist with the HRPP toolkit customization as well as training of IRB staff and members. In addition, Huron resources helped to map out the new HRPP infrastructure and provided technical guidance to assist with the design of Centralized Information Tracking System Institutional Review Board (CATS IRB) and to build a small number of customizations into the IRB product.

“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

One of the benefits of beginning with business-process change and conducting Huron-supported training of the toolkit was a better understanding of the IRB product.

Phase II: IRB System Implementation and Training and 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.

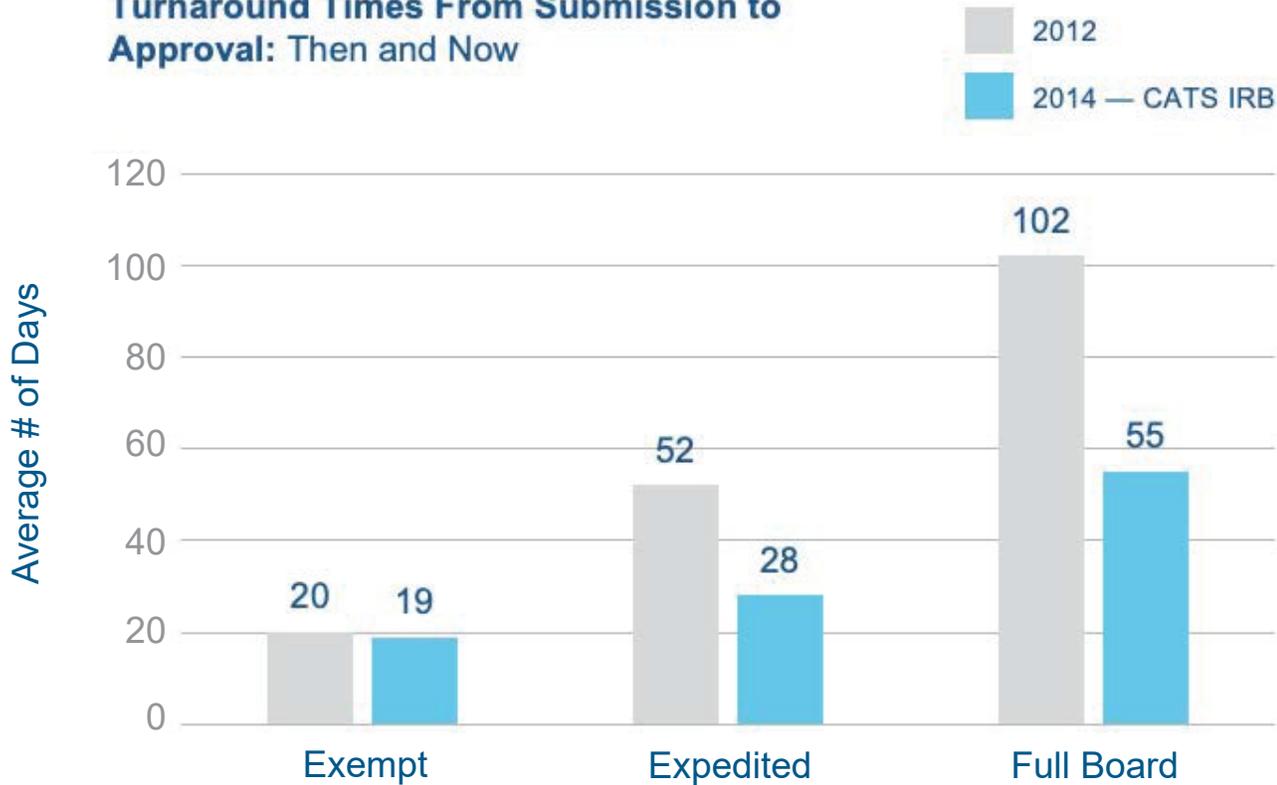
Throughout this phase, Huron provided support for ongoing training, targeted quality assurance, relevant updates to the investigator manual, data migration of existing studies from Penn State’s legacy system, integration with the clinical trial management system and development of a communication/execution plan.

Results

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

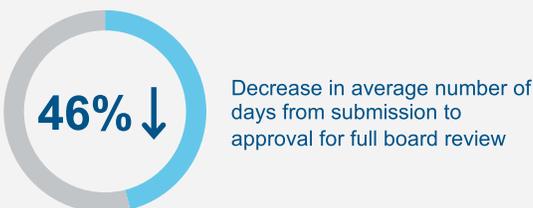
- Decreased IRB turnaround times
 - **5%** decrease in average number of days from submission to determination for exempt research
 - **46%** decrease in average number of days from submission to approval for expedited review
 - **46%** decrease in average number of days from submission to approval for 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

Turnaround Times From Submission to Approval: Then and Now



Saving Time and Improving IRB Turnaround

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



Phase III: Post-Implementation Support. The final phase of Penn State’s IRB transformation focused on addressing any outstanding questions or tasks and ensuring the institution continued to use the HRPP toolkit with CATS IRB correctly.

Specifically, Huron helped university leadership to develop internal audit standard operating procedures (SOP) and tools for the use of the HRPP toolkit, train staff to conduct internal audits of HRPP toolkit use, provide AAHRPP application assistance, and deliver project technical support for five months post-go-live.

Penn State also applied for AAHRPP reaccreditation and had the site visit 11 months after the CATS IRB go-live. There were no observations reported as a result of the site visit; 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.



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