The Problem

- Historically, the USF IRB staff worked in silos, with social behavioral staff reviewing only social behavioral submissions and biomedical staff reviewing only biomedical research. This workflow was typically sufficient until the IRB was inundated with social behavioral submissions in the Fall, or when there was a drop in biomedical submissions.

- Staff was also segregated in the types of applications they reviewed (e.g., amendments or initial applications). This became problematic when the IRB received a surge in initial applications, especially when staff who typically reviewed initial applications were on leave.

- The IRB needed to become more efficient and adapt to seasonal fluctuations in workload.

Outcomes

The IRB is now better equipped to respond to seasonal fluctuations in volume and therefore, maintain a consistently high level of customer service to our researchers. The IRB delivers competitive turnaround times during these fluctuations, and the staff has become a more unified, cohesive team with increased morale.

Implementation of IRB Staff Cross-Training

IRB administration began cross-training IRB staff. Those who primarily reviewed biomedical research began reviewing social behavioral research and vice versa.

Social behavioral IRB staff were trained to review FDA regulated clinical trials which required additional education, while biomedical staff received training in the review of student research and other areas of social behavioral research such as anthropology and psychology. Additionally, staff who were accustomed to reviewing initial submissions began reviewing applications for continuing reviews and amendments.

Discussion

When embarking on an initiative to cross train biomedical and social behavioral IRB staff, it is important to keep in mind that not everyone embraces change. When presenting the idea to staff, it is helpful to stress that each of them is an important member of a larger team that serves the research community. Additionally, IRB staff can cross train each other as opposed to having administration conduct the training.
Joining Forces: Using Education and Quality Assurance to Reduce For-Cause Audits
Julie Martin, M.Ed., RN, CCRP

The Problem:
Noncompliance among researchers is a concern for Human Research Protections Programs (HRPPs). While processing applications for continuing review, IRBs may discover study teams have:
- Used expired or unstamped informed consent documents;
- Failed to add study staff to the IRB application;
- Failed to report serious adverse events; or
- Implemented changes to the research without IRB approval.

Educating Study Teams:
The USF HRPP education and QA/QI programs joined forces to expand education initiatives to reduce noncompliance.
- Focus was on partnering with researchers, not penalizing them
- Instituted half day study team retreats on topics such as ethics in human subjects research, serious adverse event reporting, policies and procedures, and ways to avoid noncompliance
- Retreats were interactive, incorporated skits, held in convenient locations for study teams, and satisfied human subjects protection education requirements

Outcomes:
The increased efforts of the programs resulted in a significant increase in education course attendees from 2012 to 2013. In 2013, the QA/QI Program conducted routine audits which provided study teams with education pertaining to IRB policies, federal regulations, and good clinical practice and saw a reduction in IRB requests for for-cause audits.

Discussion:
While embarking on this type of program it is important to recognize that study teams are anxious when notified that they will be "audited." It may be helpful to use the term evaluation to let them know you are there to help. Study teams are often unaware they are committing noncompliance with HRPP policies or regulations. A robust education program tailored to the needs of the research community can significantly improve compliance and reduce for-cause audits.
Purpose:
Achieve consistency in IRB staff pre-review of research, especially when the research involves issues that IRB staff do not see frequently. The development of a training program for IRB staff increased consistency in review of common issues, but did not address those that are unique in nature. IRB staff needed a resource to consult when confronted with these unusual issues.

Goals:
- Improve review time
- Improve consistency among IRB staff
- Increase IRB staff confidence
- Improve overall customer satisfaction

Resource Guide Features:
- Easy-to-use Word documents
- One location to find frequently accessed information
- Customized for individual IRB staff
- Links to more detailed documents & websites
- Timely updates
- Table of contents for list of topics
- Search using Ctrl-F
- FAQ section
- Index of keywords

Development Plan:
1. Analyze problem / assess need
2. Decide on development tool
3. Test, search, hyperlink, and formatting in Word
4. Create and distribute survey to IRB staff to assess needs
5. Run metrics for baseline
6. Create an outline of topics
7. Review existing policies, SOPs, minutes, Help Desk FAQ, Management emails, IRB Staff Training program, Staff input
8. Write new tips for guide
9. Assemble and format guide
10. Pilot test resource guide
11. Distribute resource guide to staff & training
12. Distribute second survey to gather feedback on guide
13. Run metrics to assess improvement of processing time

Future Outcomes:
- Complete development and assess improvements
- Commercialize generic guide for other IRB sites
- Commercialize customized guide for other IRB sites