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Protocol-Specific Training in a Commercial IRB World: Adjusting the Process to Ensure Training Keeps Up

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1. Background

Protocol-specific training is essential for staff delegated study-specific duties on clinical trials. Training prior to study activation and amendment implementation is imperative to protect patient rights and safety, to ensure staff understand their roles, and to avoid protocol deviations.

Historically, our training timelines have been based on the rate at which our institutional IRB processes approvals. Staff were first trained on a protocol after initial IRB approval and prior to working on a trial. Amendment training was administered after IRB submission, and the orders and budget teams were often notified of an amendment after approval.

Amendments are implemented within 2 business days of IRB release. However, with the speed at which commercial IRBs are processing amendments, the submission to implementation windows have greatly diminished. Furthermore, when a commercial IRB acts as the central IRB, our site is often notified of an amendment at the time of approval. Our system did not allow adequate time to revise treatment orders, train delegates, or update study budgets prior to amendment implementation.

2. Goals

- Identify barriers to meeting protocol-specific training objectives
- Decrease the number of staff without training prior to study activation and with delayed amendment training
- Eliminate late modifications to orders and budgets
- Develop tools for consistent documentation of training
- Educate on staff responsibilities
- Assess staff compliance with the updated process

3. Solutions and Methods

We formed a task group of education, quality assurance (QA), clinic, regulatory, finance, and orders staff to discuss current workflow and obstacles. We determined that the swift approvals from commercial IRBs requires earlier communication and training.

Initial training is now administered as soon as training materials (e.g. training slides) are available. Staff are not added to the DOA log until initial training is complete. Within 2 days of amendment receipt, we initiate an OnCore Task List to facilitate communication between the regulatory, clinic, budget, and orders teams. If required, delegates are trained on an amendment within 5 business days of OnCore Task initiation. When we receive an amendment at the same time as IRB approval, training is distributed immediately.

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We created standardized tools and templates to communicate and document training. We created work instructions outlining the responsibilities of each staff member. We educated staff on process changes during in-person education sessions, followed by an online module and assessment.

In order to assess staff adherence to the process updates, QA added reviews of the process to routine audits, and supervisors were trained to run OnCore Task reports.

4. Outcomes

The orders team is now able to review amendments within 24 hours of the OnCore Task initiation. The budget team has seen a marked improvement in how quickly they can complete updates. Regulatory has noted an increase in staff trained prior to study activation.

5. Lessons Learned

- Training staff with entrenched habits is difficult.
- Staff and faculty feedback facilitates streamlined workflows.
- Simpler and concise tools are more useful to staff.
- More data from supervisor reports and QA audits will inform next steps.

We will continue to assess the feasibility of the process and the utility of the tools, and work to develop innovative ways to administer continuing education.