BACKGROUND

Traditionally, our institution’s IRB used a “home grown” software tool called the Research Management System (RMS) to manage IRB workflow. Intermountain conceptualized and developed RMS in 2003 as the principal software tool for managing our research applications. After 9 years of development, the project failed to accomplish its goals. During the past two years, IRB staff started noticing frequent error messages, complaints from researchers regarding missing documents and non-intuitive processes, burdensome and time-intensive applications and similar concerns, adding complexity to the already challenging IRB review process. This made workflow management in the IRB office difficult. Our institution had, in addition to using the electronic system for submission and approval of applications, been utilizing a paper-based review model for IRB board meetings. The cost and inefficiency of printing, copying, and shipping paper packets to IRB committee member became unsustainable. Moreover, our current system did not capture some of the data essential to tracking and generating important department reports. We decided to purchase a new software management tool that could replace the outdated application management tool and the paper-based board review model.

METHODS

First, we conducted a thorough review and evaluation of new software tools. We spent 6 months reviewing our initial list of available options and narrowed the list down to 3 potential programs. We created a workgroup of staff from a diverse set of research departments. The workgroup evaluated each of the top 3 selections and selected the final product. The IRB staff, as well as a group of “super-users” gave input on the design and customization of the new software tool. Also, a representative from the system vendor provided our staff with basic user training.

We developed an implementation plan and distributed it system-wide via standard corporate communications channels. The implementation process took longer than expected due to compatibility issues between our institutional security systems and the new software. We decided to overlap the use of our old system with the new system until the new process was fully functioning. One of our main concerns was that our IRB committee members were used to paper-based reviews. We distributed an online questionnaire to learn more about committee members’ training preferences. We instituted open office hours at two of our main facilities and established a generic email account for support requests from researchers. We trained IRB staff members to respond to customer inquiries, and designated one of our staff members as the primary contact for calls related to the implementation. We worked with our corporate communications department to relay information and updates to our research community throughout the process. IRB committee members trained via a) group instruction following IRB meetings, b) 1:1 training sessions, and c) instruction manuals developed for this purpose.

RESULTS

Following implementation, we surveyed staff, researchers, and committee members to solicit input on what was or was not working well. Staff members logged trouble-shooting calls and tracked issues to identify major problems and common questions asked. We have implemented ongoing monitoring that will remain in place until 2015, and then reevaluated.

LIST OF CONCERNS WITH RMS

- Incomplete function of the IRB modules requires IRB staff to manage duplicative processes to ensure regulatory compliance.
- Processes for submitting adverse event reports, protocol deviations and other compliance issues are still not automated.
- Reviews are not forwarded to board members electronically within the system, but require a separate paper or email process. Reviewers must also complete paper reviewer forms and return these to the IRB office for regulatory file, thus creating a duplicate workflow process for the IRB staff.
- Lack of Audit Trails; both for workflow and compliance monitoring.
- Researchers/users are unable to login to system and see the status of their project or see “at a glance” if any action is required on their part.
- Lack of flexibility to change and update application questions and modify forms.
- Required Human Subjects Research Educations not tracked within the system.

INITIAL NEEDS-ASSESSMENT

- Provide measurement of operation statistics and audit trail, including:
  - Individual employee workflow management
  - Tracking approval and review timelines
  - Tracking data related to study filings
  - Compliance monitoring

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- Eliminating unnecessary and duplicative steps.

- Automate the protocol review and approvals process.
- Help ensure compliance with Intermountain policies and procedures, and current regulatory requirements from the FDA/other government regulations.
- Ensure event reporting compliance.
- “Forced” workflow to prevent errors.