Developing Timely & Appealing Human Subject Protection Refresher Education Using Education Program Participation, Unanticipated Problem & Internal Audit Data
Susie Corl, MSW, MPH, CIP, CCRP and Matt Stafford

What is the Human Subject Protection Education requirement?
The IRB requires that researchers complete a basic human subject protection course, as well as a 3-year ‘refresher’ course.

What courses are available? What do Researchers Choose?
The basic course is a commercial, online course. Refresher options include an abbreviated commercial course, and institution-based courses provided by the IRB and the Education & Quality Improvement Program (EQuIP).

What data about common problems and successful preventive and corrective actions is available?
The institution-specific course content is customizable and can be updated regularly to include timely content with the goal of preventing common problems. Data about common, preventable problems and best practice corrective actions is collected as a part of both IRB and EQuIP business.

Percent Participation in Refresher Course by Category

29% Commercial
71% Institution-based

Rounds/Discussions – Target specific professional categories, physicians, nurses, study coordinators
Intro to Clinical Research Course – Multiday course for New Investigators
* EQuIP Study Review – Educational Audit of a study, credit provided to study team members who participate
* EQuIP New PI – Individual training with first time BCH PI to review responsibilities
Dept Meeting – Standing Meeting, presentation requested by Dept

Number of Researchers Participating

50
33
64
160
68

*Two of the courses are currently required for and usually only offered to a subset of the research community.

Lessons Learned & Next Steps

Clean
the available data

- Miscategorized data – qualitative review of UP data identified a number of significant protocol deviations that should have been reported in the medication or lab error category
- Skewed reporting – one study accounted for half of the significant protocol deviations reported during the specified time period
- Cross reporting – some issues were reported in more than one UP category

Improve
data collection methods

- Clearly categorize and operationally define any UP data entry options and provide clear instructions to improve consistency of self-report
- Consider how internal audit observations are measured and categorized to make problem categories clear and minimize inter-rater variability. This can make outcome data more useful for educating target audiences.

Offer more accessible
Institution-based education

- The EQuIP New PI training content is customized to the study and updated with new policy/regulatory/UP trend information, but is currently only offered to and required of “New” PIs prior to study initiation. The content of the course is being transferred to an online format, with plans to re-market it as a Refresher Education option.

Consider
all available data sources

- Qualitative data – Access researcher participation feedback from education course evaluation data and other existing research quality improvement initiatives that collect suggestions for education content
- Other IRB submission data – Researchers submit minor protocol deviation logs with continuing review or study close-out submissions.