

Research Compliance Education and Training Programs: Responding to a New Regulatory World

Mindy J. Steinberg, MPH, and
Elaine R. Rubin, PhD

Strategic approach required to address infrastructure, leadership, curriculum, and communication needs.

Education and training programs have long been integral to clinical research at academic health centers. However, a new world of regulation, with an ever-increasing number of mandates and requirements for institutions and staff, is changing the nature and scope of the education and training function. Clinical research, a major part of the vast biomedical research enterprise within academic health centers, is framed by institutional administrative structures developed to manage a complex web of policies, procedures, and regulations that affect thousands of personnel. Given heightened concerns about compliance, accountability, and liability, along with a concurrent movement toward administrative integration within academic health centers, education and training programs are undergoing assessment and change.

While education and training was originally focused on the ethical conduct of research, today education and training includes a broad range of topics from the basics of protocol and study design to budgeting, billing grids, and billing compliance. Education and training programs have expanded to include technical and operational topics designed to ensure that faculty and staff are knowledgeable about the myriad institutional policies and practices, as well as state and federal regulations, which apply to clinical research, thus making education and training a major link between all research and compliance functions.

In this changing environment, there is increasing interest in the organization, structure, and management of research compliance education and training, including leadership, planning, the scope of offerings, resources, and future priorities for the academic health center.

To examine the nature of the education and training function and options for the future, the Association of Academic Health Centers (AAHC) conducted informal interviews with chief compliance officers and research administrators



Association of Academic Health Centers®

Leading institutions that serve society

“In this changing environment, there is increasing interest in the organization, structure, and management of research compliance education and training”

at selected member institutions—both public and private—with research portfolios of varying sizes. Questions were asked about the administration, management, and scope of programs, as well as policies, infrastructure development, curricula, and communication related to education and training programs. The findings highlight a critical function within the academic health center undergoing evolution and development to accommodate changing institutional structures and new regulatory demands.

FINDINGS: COMMON THEMES EMERGE

From the interviews, several prevailing themes emerged regarding the current state of clinical research compliance education and training at academic health centers. Although the institutions included in this project varied significantly in size and structure, similarities abounded among the issues each institution is confronting with respect to research compliance education and training.

Infrastructure Highly Decentralized and Leadership Responsibilities Dispersed

The discussions revealed that the clinical research education and training function is highly decentralized. In many cases, one office serves as a clearinghouse for information about the various training opportunities available throughout the institution, but it is rare for any one office to have complete responsibility for and authority over all of the training at the institution. The responsibility for clinical research education programs is spread throughout the institution, dispersing the evaluation of risk and the programs to address that risk.

Subject matter drives the programs and administration of the education and training function, dividing training among different departments and schools based on the topics

being covered. Individual training offerings can be under the auspices of the institutional review board (IRB), the office of research administration, the compliance office, the office of human subject protection, the grants and contracts office, various hospital departments, and/or the various billing departments.

The lack of consolidation of education and training programs is further demonstrated by a general inability of chief compliance officers to quantify expenditures and human resources allocated to education and training. Most of the institutions profiled reported that the responsibility for the development and facilitation of education and training offerings is included in the job descriptions of many employees, but it is rare for any one employee to spend the majority of his or her time on education and training work.

Several of the compliance officers reported that their education and training programs are in the early stages of development and many are in the midst of expanding programs and offerings. The progress these compliance officers had already made on the establishment of these programs was greatly facilitated by the support and direct involvement of senior leadership.

Curriculum Development Diffused: Offerings Expanding but Inconsistent

Responsibility for the development of training topics is diffused throughout the institution mirroring the decentralized infrastructure for education and training. Several compliance officers noted that they look to “experts” within the institution on the particular topic(s) to be covered to develop training curriculum. Compliance officers noted that very few standardized education modules are available to help develop training programs.

It was reported that educational offerings are developed when new regulations are implemented or when problems are found through regular audits, rather than in a strategic fashion in anticipation of a changing landscape or program evaluation. Training on human subject research and the protection of research participants is the only topic that was offered at every institution profiled. A few other topics are offered at almost all of the profiled institutions, including the basics

of clinical research compliance, effort reporting, and the HIPAA Privacy Rule in research. Only one institution did not offer HIPAA training because it is not a covered entity and therefore not subject to HIPAA.

Some training topics are growing in popularity and are offered at the majority of the institutions profiled, but many of those topics are somewhat new. Some of these topics are conflict of interest, research ethics, protocol and study design, and a variety of offerings related to clinical trials billing—budgeting and billing grids, advanced budgeting and negotiation, and billing compliance. Training on billing topics is more often offered at institutions with large research portfolios. At some of the profiled institutions with small research portfolios, compliance officers noted that, thus far, they have only done studies that are wholly financed by the sponsor and have not yet had to deal with any third-party billing in clinical trials. Clinical trials billing at these institutions is less complex and does not require extensive education and training.

Training is offered to a broad range of stakeholders, including principal investigators, study coordinators, other members of the research team (e.g., study nurses), billing personnel, administrators, coders, and clinical scheduling personnel. Less than half of the institutions profiled made their training available to all faculty or staff at the academic health center. Training is most often offered to the research staff (e.g., PIs, study coordinators, and other members of the research team), as well as billing personnel.

Mandatory Training: Variability in Job Descriptions Complicates Expansion

Mandatory training for the various research constituencies (e.g., principal investigators, study coordinators, billing personnel) varies significantly within each institution and from institution to institution. Compliance officers reported that certain topics are more amenable to creating mandatory training than others. For instance, at all the profiled institutions all staff working on a new protocol must complete human subject protection training as a condition of IRB approval of that protocol. Training on the HIPAA Privacy

Rule is another topic that is often mandatory, and is frequently required of all academic health center faculty and staff regardless of job function. Two of the profiled institutions specifically noted that training on effort reporting is mandatory and those employees who do not complete the training in a timely fashion risk having their research or their salary suspended. In addition, some of the profiled institutions reported that individual departments in different schools within the university (e.g., medical school, graduate studies) require their faculties to complete specific training modules even though they may not be mandatory institution-wide.

Many of the interviewed compliance officers expressed interest in expanding the number of offerings that are mandatory beyond the usual topics, and in linking the completion of mandatory training to job performance evaluation. Only one of the profiled institutions reported that the vast majority of its education and training offerings are mandatory. Complicating the process of expanding mandatory offerings is the significant variability in job titles and job descriptions, as well as a high turnover in research staff, according to most compliance officers profiled.

It was noted that without standard job titles and job descriptions, it has been difficult to systematize which employees must complete which trainings. Without this kind of system in place, institutions appear reluctant to begin linking education and training with job performance for fear of uneven application across the institution. High turnover of research staff, particularly study coordinators, further complicates the expansion of mandatory training offerings by significantly increasing the number of employees requiring training at any given time.

“Many of the interviewed compliance officers expressed interest in expanding the number of offerings that are mandatory beyond the usual topics, and in linking the completion of mandatory training to job performance evaluation.”

Maintaining Records: A Complex Web Without Innovative IT Solutions

Gathering and maintaining information on which training courses each employee needs and has completed is an extremely labor intensive task and is often not automated. Two institutions profiled by the AAHC have built software systems that synthesize what education and training is required of each employee or new hire based on his or her specific responsibilities. The IT systems have the capability to send periodic updates to the employee and his or her supervisor detailing completed and unfinished training modules. These systems are homegrown and may be cost-prohibitive for institutions with small research portfolios.

Training Mechanisms: Standardization is Limited

The delivery methods and educational techniques used in education and training varied significantly within the academic health centers profiled. Formats include one-on-one, small group workshops, large group lectures, and internet-based training. Virtually all of the institutions have in place, or are in the process of transitioning to, a significant portion of their education and training in a web-based format.

Frequently, the topics most in demand and those that are mandatory are the courses offered via the internet in an effort to accommodate the schedules of a greater number of faculty and staff. For instance, human subjects research training is the most common web-based training. Most of the institutions use the Collaborative Institutional Training Initiative (CITI) program, a collection of web-based training modules on the protection of human subjects developed by the University of Miami and the Fred Hutchinson Cancer Research Center in Seattle, Washington. The CITI training is the only widely used, standardized module for research compliance education and training. Other delivery methods, such as one-on-one sessions, small group workshops, brown bag lunches, and large group lectures are offered at many of the institutions, but the methods varied by topic and participants in the training.

Perceptions of Education and Training

There was a general consensus among the compliance officers profiled that they had the most difficulty engaging principal investigators in education and training. Among the reasons given were that principal investigators are difficult to reach, extremely busy, and traveling often. Compliance officers also reported having difficulty engaging some of the other research staff in education and training due to high staff turnover. Research administrators and clinical research study coordinators were noted by the majority of compliance officers as the groups most interested in training and most receptive to new offerings. The profiled compliance officers were generally split in their perceptions of their ability to reach post-doctoral fellows. Some of the officers reported post-docs being extremely receptive to training offerings while other institutions had established special programs to work with post-docs to combat the difficulties previously faced reaching that group.

Communicating Training Opportunities

The compliance officers were asked if their institution had a communications plan designed to keep the necessary stakeholder groups aware of training opportunities and requirements. Only one of the institutions profiled had a formal communications plan in place and it is in its early stages of roll-out. The other institutions reported no formal plans and primarily rely on the education and training program's website along with listserves, emails, and flyers to communicate news and information about training offerings.

Limited Availability of Resources

Most profiled institutions expressed an interest in learning about the education and training programs at other institutions to assist in future development. However, those same institutions have limited resources to gain that information and few standardized modules are available to work from. More often than not, compliance officers reported "recreating the wheel" when they developed their education and training

offerings. Some also mentioned the competition for resources within the institution and expressed concern that a drop in resources for education and training could make it difficult to maintain the quality of the programming offered. The officials were concerned that if faculty and staff heard through word of mouth that training was of poor quality, then encouraging attendance would become extremely difficult.

Time Constraints and Regulatory Environment Create Barriers

Time was the second greatest barrier, after decentralization, to the success of the education and training program, according to the chief compliance officers. Principal investigators and research faculty often view training as an unnecessary time constraint and a distraction from their research. Compliance officers reported that researchers feel that they already understand the relevant issues and that additional training is redundant. Some of the compliance officers interviewed said that while it would be ideal to have PIs, research staff, and others in day-long seminars on some of the more complicated training topics, it simply was not feasible to expect people to be able to leave their work for that long.

New rules and new guidance on existing regulations that have a bearing on biomedical research are issued on a regular basis from several different federal agencies, including the Centers for Medicare & Medicaid Services (CMS) and the Food and Drug Administration (FDA). As the new rules are promulgated and new guidance is issued, the institution has to develop new procedures for compliance and ensure that all necessary faculty and staff are made aware of the changes. Furthermore, these regulatory mandates are often unfunded and require a significant investment of resources by the academic health center.

Factors That Facilitate Education and Training Programs

When asked to list factors that make providing education and training programming easier, compliance officers overwhelmingly mentioned strong support and buy-in from senior leadership as the most important factor enhancing the

education and training function. They noted that when communications come exclusively from the compliance office, resistance is often sometimes encountered because the office is viewed as purely serving an enforcement function. Other facilitating factors include a stable IRB membership and access to the CITI training, a standardized module that does not require any additional staff time for development.

CONCLUSIONS

The AAHC interviews identified areas of concern with respect to clinical research compliance education and training programs and highlighted major constraints to program implementation and expansion, including infrastructure, leadership, communications, curriculum, delivery methods, resources, and time. The interviews particularly revealed little strategic planning with regards to education and training, which also contributes to current stresses and hampers coordinated future development. However, it should be noted that many of the education and training programs examined for this issue brief are in the early stages of development and compliance officers are still grappling with finding ways to keep their programs in the vanguard with the ever-changing field of clinical research compliance.

Decentralized Functions Can Hamper Effectiveness

As evidenced by the responses, education and training is diffused throughout the academic health center infrastructure, often diminishing its visibility and weakening its effectiveness. Decentralization of the clinical research education and training function appears to have led to significant variation in standards, content, and delivery methods, and hampers the ability of the institution to look strategically at the function as

“As evidenced by the responses, education and training is diffused throughout the academic health center infrastructure, often diminishing its visibility and weakening its effectiveness.”

a whole. Decentralization of the function across the institution seems to significantly decrease efficiency, increase duplication, and limit the ability of research administrators to focus more on strategic planning.

With education and training spread across the institution, and with no one employee or office with direct responsibility for all activities, it appears that those with responsibilities for education and training are creating programs that are reactive and crisis-driven, rather than proactive and motivated by the changing demands of the research enterprise.

Compliance officers perceive the decentralization of the education and training function as having a negative impact on the curriculum and offerings because the infrastructure does not provide a framework for strategic planning or the development of new processes and procedures with respect to education and training. The development of new training offerings, therefore, appears to become focused around the buzz of the moment rather than the needs of the institution and the changing realities of the research enterprise. Furthermore, the wide variation in job titles and descriptions, which make it extremely difficult to determine which training is appropriate for which employee, is viewed as hampering the ability of institutions to accurately assess which courses need to be mandatory, as well as expand the mandatory training courses. Institutions are increasingly struggling with the many variations in job descriptions as they try to make training on more topics mandatory and link completion of necessary training to job performance.

Time constraints of faculty and staff further complicate the problems caused by decentralization of the function. However, the multiple competing demands on the time of faculty and staff and an ever-changing regulatory environment are larger problems that cannot be addressed solely through the education and training function.

“Leadership is viewed as critical to the success of the education and training function.”

Senior Leadership Participation is Critical

Leadership is viewed as critical to the success of the education and training function. Direct involvement of senior leadership in education and training is considered a key factor in easing efforts to consolidate the function across the institution, and ensuring that adequate resources are allocated to education within the larger research enterprise.

The education and training function suffers from a lack of visibility within the academic health center, resulting in low prestige and limited decision-making power. A lack of consolidation of the education and training function results in faculty and staff perceiving the function to be of limited importance, according to some interviewees.

A Strategic Communications Plan is Key

Communications is rarely addressed in a strategic fashion. Only one profiled institution has a strategic plan for communications; the others have none. Communications is primarily viewed in terms of dissemination of information, tools to use, and tasks to accomplish. Most of the profiled institutions, for example, rely primarily on a website to disseminate information about education and training offerings. Difficulties in engaging some of the important research constituencies in the full scope of education and training may also reflect how the lack of strategic communications planning has had a detrimental impact on the function's image and significance within the academic health center. A perception that education is low in the hierarchy of importance can risk having needed resources reallocated to other areas of the institution and limiting the capabilities of the education function.

Communications related to research compliance education and training has not been viewed as a management issue that requires systematic planning and the establishment of a framework for information flow and image development. However, such an approach could particularly allow institutions to address perceptions and concerns of target audiences, including the view that compliance offices only

“Communications is rarely addressed in a strategic fashion.”

deal with enforcement, and enable them to work with all stakeholders to identify and implement viable communication options.

Continuing Evaluation can Monitor and Guide Program Development

Chief compliance officers were not asked questions about the evaluation of education and training programs. However, there is some concern that a variety of factors, including the decentralized nature of the education and training function, are limiting the institutions' ability to adequately monitor and evaluate training offerings. Through evaluation, compliance officers can gain needed feedback on participants' perceptions of the quality of training, assess the usefulness of the information provided, and determine how that information is being applied in the research context. The inability to do this kind of evaluation may be having unintended consequences. For example, as many institutions attempt to strike the balance between education and training and the time constraints of faculty and staff, they may be compromising the quality of the education by transitioning to more online trainings that are less time intensive and more flexible to researchers' schedules. These methods used to accommodate the needs of researchers may also be minimizing perceptions of the importance of the information and lowering standards for the comprehension and retention of the information.

RECOMMENDATIONS

This examination of the education and training function at academic health centers highlights many critical, interrelated issues that have not been addressed in a comprehensive, systematic fashion to date, and which require attention as clinical trials administration undergoes change. Based on the AAHC findings and the ongoing and increasing demands on this research function, the AAHC recommends that academic health center leaders and research administrators:

- Engage key stakeholders to develop and implement a comprehensive, institution-wide, strategic plan for the education and training function at the academic health center that addresses:
 - The structure and organization of the education and training function and the opportunities for consolidation within one office and/or under one senior administrator with direct responsibility for all institutional programs;
 - Educational and training leadership requirements to ensure that the office or individual appointed to oversee the education and training function has a working knowledge of the clinical research enterprise, regulatory compliance, and adult learning strategies;
- Incorporate a strong communications plan into the strategic plan that considers the needs of all major research constituencies, particularly principal investigators and others with multiple responsibilities and time constraints;
- Address human resource policies and procedures creating barriers to education and training, and develop plans to standardize job titles and descriptions to assist the institution in its strategic analysis of educational offerings and educational effectiveness and efficiencies;
- Explore creative solutions, including but not limited to technologies, to engage more constituencies and make learning more efficient and effective;
- Develop and implement an evaluation plan to actively monitor the success of training offerings, delivery methods, and educational techniques; and
- Establish mechanisms to collaborate across the academic health center community and share innovative ideas for improving education and training.



Association of Academic Health Centers[®]
Leading institutions that serve society

VISION

To advance health and well-being
through the vigorous leadership of
academic health centers.

MISSION

To mobilize and enhance the strengths
and resources of the academic health
center enterprise in health professions
education, patient care, and research.

1400 Sixteenth Street, NW, Suite 720
Washington, DC 20036
202.265.9600
202.265.7514 fax
www.aahcdc.org

For more information, contact:

Mindy Steinberg, MPH, Program Associate, msteinberg@aaahcdc.org

Elaine Rubin, PhD, Vice President for Policy and Program, erubin@aaahcdc.org

© 2009 by the Association of Academic Health Centers