Carome, Michael A (HHS/OPHS)

From: Irena Tartakovsky [itartakovsky@aamc.org]
Sent: Friday, September 26, 2008 6:02 PM
To: PSC Humansubjectstraining
Cc: Susan Ehringhaus; Carol Blum; Pat White; Norton, Leah
Subject: COGR, AAU, AAMC Comment Letter to OHRP's RFI on the Implementation of Human Subjects Protection Training and Education Programs

Attachments: OHRP_RFI_Training and Education_Comments_COGR_AAU_AAMC-092608.pdf

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Attached, please find the comments of the Council on Governmental Relations (COGR), the Association of American Universities (AAU) and the Association of American Medical Colleges (AAMC) on the OHRP's RFI on the Implementation of Human Subjects Protection Training and Education Programs.

The text of our letter is also copied in the message below. Please let me know directly of any difficulties in transmission.

.....
Irena Tartakovsky, M.D., M.S.
Sr. Science Policy Analyst
Biomedical and Health Sciences Research
Association of American Medical Colleges 2450 N Street NW, Washington DC 20037
Tel: 202-862-6134
Fax: 202-828-1125

Captain Michael A. Carome, M.D.
U.S. Public Health Service
Office for Human Research Protections
1101 Wootton Parkway, Suite 200
Rockville, MD 20852

RE: Human Subjects Protection Training and Education Programs,
Request for Information and Comments

Dear Dr. Carome:

The Council on Governmental Relations (COGR), the Association of American Universities (AAU) and the Association of American Medical Colleges (AAMC) appreciate the efforts of the Office for Human Research Protections (OHRP) to engage the public in a dialog and welcome this opportunity to comment on the notice entitled: "Request for Information [RFI] and Comments on the Implementation of Human Subjects Protection Training and Education Programs."

COGR is an association of more than 175 research universities and their affiliated academic medical centers and research institutes. COGR concerns itself with the influence of federal regulations, policies and practices on the performance of research and other sponsored activities conducted at its member institutions.

The Association of American Universities comprises 60 leading U.S. research universities, which together perform 60 percent of federally funded university-based research.

AAMC is a not-for-profit association representing all 129 accredited U.S. and 17 accredited Canadian medical schools; nearly 400 major teaching hospitals and health systems, including 68 Department of Veterans Affairs' medical centers; and 94 academic and scientific societies. Through these institutions and organizations, the AAMC represents 109,000 faculty members, 67,000 medical students, and 104,000 resident physicians.

We share OHRP's view of the importance of training and educational programs for the individuals involved in the conduct, review or oversight of human subject research and we have pursued a variety of mechanisms to ensure that this training and education occurs at our institutions. However, we do not believe that a change in the regulations mandating training is necessary or appropriate at this time.

The background information provided in the RFI as a rationale for proposing such a change is useful and interesting from a historical perspective. Nonetheless, we do not believe it reflects the evolution of educational programs at our institutions. Since the HHS Office of Inspector General (OIG) 1998 Report "Institutional Review Boards: A Time for Reform,'' the community has instituted mechanisms and approaches to education and training. Institutions have developed programmatic initiatives including seminars and workshops delivered in a variety of settings and approaches to train investigators, Institutional Review Board (IRB) members and administrative staff as well as research participants to ensure the protection of human subjects. In addition to these unique, local opportunities, institutions have invested in the development of their professional staff and their human participant protection programs as a whole.

For example, as of June 2008, 129 organizations, representing 550 entities have earned voluntary accreditation of their human subjects protection programs through the Association for the Accreditation of Human Research Protection Programs (AAHRPP). Since 1999, over one thousand individuals have been certified under the Public Responsibility in Medicine and Research's (PRIM&R) Certified IRB Professional (CIP(r)) program. Finally, as of August 2008, more than 900 institutions have participated in the training programs provided by the Collaborative Institutional Training Initiative (CITI) Course in the Protection of Human Research Subjects. These processes and programs materially supplement those that our institutions routinely offer to ensure that those involved in human subjects research meet applicable federal and state requirements.

Assurance through FWA

We support the existing approach of a recommendation from OHRP through the terms of the Federalwide Assurance (FWA) regarding education. The FWA is the instrument used for assuring that the institution meets the requirements regarding human subject protections and OHRP's endorsement of training as one measure or mechanism for meeting the terms of the assurance is appropriate. We strongly oppose any additional regulations on the issue of human subject protection training and education.

We do not believe that noncompliance is, necessarily, a reflection of a lack of training. Compliance is a result of a variety of factors including comprehensive training and the development of a culture of compliance within an institution achieved by providing adequate support to investigators, maintaining effective oversight and, finally, holding individuals accountable for their performance. All of these elements that lead to compliance are appropriately managed at the individual institution level, not imposed through regulatory imperative.
Therefore, we believe that the existing framework is fully adequate in its reliance on the FWA's strong recommendations for training and
education. We are unaware of any study assessing whether institutions
have or have not "routinely implemented OHRP's recommendations" and until such a study is completed and analyzed, the role of training as a contributing factor to non-compliance is purely speculative and cannot serve as a basis for additional regulations.

Scope and Content of Training

It is extremely difficult if not impossible to meaningfully prescribe through regulation either content, frequency, or adequacy of training.
We agree that individuals involved in the conduct, review or oversight of human subject research should know and understand their responsibilities within the process. We believe that individuals should receive initial training appropriate to their roles prior to any

involvement in the conduct, review or oversight of human subject research. However, due to broad variability in job categories and the responsibilities of involved individuals, any prescriptive requirements would be impractical and unworkable. Institutions are best able to determine the content and extent of relevant training according to an individual's role in the research process. Continuing or ongoing appropriate training and educational activities should be offered to individuals as roles and circumstances, including regulations, change, but we strongly oppose arbitrarily prescribed or recommended intervals for training programs.

Increased Documentation

New regulations calling for written documentation on training completion or procedures for implementing training programs or monitoring the training of individuals involved in human subject research are unnecessary and add significant bureaucratic and unfunded record-keeping requirements without enhancing the protection of subjects and should not be implemented.

Cost of Compliance

The costs related to compliance with the Federal regulations governing human subjects research have increased exponentially since 1995. In a survey COGR conducted in 2001, member institutions reported average increases in the cost for their human subjects protections programs of 176% between 1995 and 2000. The time commitment by faculty and staff to meeting the requirements grew substantially as well with average commitment in hours rising 141% from 1995 to 2000. With the introduction of the National Institutes of Health training requirement in 2000, we asked the participating institutions to provide actual and/or estimates of costs to meet this requirement. Institutions estimated expenditures on average of $255,000 in the next fiscal year to meet the then-new NIH requirement. These costs are not recovered by the institutions through their Facilities & Administrative (F&A) cost recovery (indirect costs) because of the cap of 26% imposed by the Office of Management and Budget in 1995.

A change in the regulations would, without question, result in substantial additional costs to our institutions. The cost of implementation of any new regulations would be in addition to these already considerable expenses that our institutions incur in conducting human subject protection training. The institutions would face these additional, unfunded costs at a time when, due to the stagnant NIH budget as well as economy in general, institutions are struggling to raise funds necessary to sustain teaching and research.

OHRP Contribution

Some institutions would welcome OHRP collecting and making available to all institutions links to educational programs that have been developed by individual institutions and academic societies. A number of major research institutions and societies have extensive, well-developed, multi-module training programs allowing flexibility and scalability of training requirements. Furthermore, to promote institutional educational efforts, the OHRP could expand mechanisms to fund the development of training tools and modules at the national levels.

We appreciate the opportunity to comment on the OHRP notice entitled: "Request for Information and Comments on the Implementation of Human Subjects Protection Training and Education Programs." Please feel free to contact us should you have any questions about our comments or if we can be of further assistance.

Sincerely,

Darrell G. Kirch, M.D. President and CEO Association of American Medical Colleges (AAMC)	Anthony P. DeCrappeo President Council on Governmental Relations (COGR)	Robert M. Berdahl, Ph.D. President Association of American Universities

September 26, 2008

BY ELECTRONIC MAIL: humansubjectstraining@hhs.gov

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Darrell G. Kirch, M.D.
President and CEO
Association of American Medical Colleges (AAMC)

Anthony P. DeCrappeo
President
Council on Governmental Relations (COGR)

Robert M. Berdahl, Ph.D.
President
Association of American Universities

Carome, Michael A (HHS/OPHS)

From: dpollock@buffalo.edu
Sent: Saturday, September 27, 2008 10:02 AM
To: PSC Humansubjectstraining
Cc: Carome, Michael A (HHS/OPHS)
Subject: Human Subjects Protection Training and Education

Dr. Carome:

In response to the OHRP request for comments on the Implementation of Human Subjects Protection Training and Education Programs, I would like to endorse the comments submitted this week by Dr. Zachary M. Schrag. Prof. Schrag's thoughtful proposals reflect considerable deliberation and insights into human subjects protection issues for social sciences, and I cannot offer a better set of observations and suggestions than his.

Sincerely,

Dr. Donald Pollock, Chair
Department of Anthropology
State University of New York at Buffalo
380 MFAC
Buffalo, New York
USA 14261

716.645.0402 [Chair's Office]
716.645.3080 [Personal Office]
716.645.3808 [Fax]

dpollock@buffalo.edu

Carome, Michael A (HHS/OPHS)

From: Liz Wool [lizwool@qd-qts.com]
Sent: Saturday, September 27, 2008 10:03 AM
To: PSC Humansubjectstraining
Subject: re: Human Subjects Protection Training and Education Public Comment
Attachments: OHRP PUblic Comment_Education and Training _27 Sept 2008_lwoolqd-qts.com.pdf

Good day,

Please find attached my public comment on this proposed OHRP Regulation.

Thank you.

Liz Wool, RN, BSN, CCRA, CMT
President and CEO
QD-Quality and Training Solutions, Inc. ™
Everyday, quality and training solutions™

1001 Bayhill Drive, Suite 200
San Bruno, CA 94066
USA

Office: 650.616.4199
Fax: 650.728.7987
www.qd-qts.com

QD-QUALITY
& TRAINING SOLUTIONS™
Everyday, quality and training solutions™

27 September 2008

Office of Human Research Protections
Public Comment: Human Subjects Protection Training and Education

To whom it may concern:

In the last decade, clinical researchers have conducted clinical trials whereby their lack of knowledge of human subject protections embodied in Good Clinical Practices and ethical conduct for research (Belmont Report, Declaration of Helsinki) has resulted in clinical trial misconduct and subject deaths. Notably, these cases were reported in both our news media and professional publications. These cases, Jesse Gelsinger (1999, University of Pennsylvania, Gene Therapy Program) and Ellen Roche (2001, Johns Hopkins Hospital) were inspected by both the FDA and the Office of Human Research Protections (OHRP) with the identification of a broken system of clinical research oversight and human subject protection. These findings document that our 'System of Shared Responsibilities' was gravely broken at these institutions. Granted, since these occurrences, these issues have been addressed by both institutions, however, the 'broken systems' could have been prevented with proper training on human subject protections, GCP training and additional topics. Since these landmark events, clinical researchers continue to not understand their responsibilities and how to implement these responsibilities in clinical trials hence we continue to see institutional and investigational site regulatory inspections identifying significant issues in the conduct of clinical research.
Establishing mandatory training for clinical research does have precedent in both US based medical practices and the US product development regulations. Firstly, in the US Code of Federal Regulations, training and training documentation is a requirement in both Good Manufacturing Practices (21 CFR 201 and 210, QSR) and Good Laboratory Practices (21 CFR 58) for the activities and personnel employed in these non-clinical specialties. It is now time to bring the same level of requirements, standards, and performance to the GCP arena, which is much closer to ensuring subject safety than the production of investigational products and animal studies. Secondly, as a Registered Nurse, my nursing school training was multi-tiered before I was allowed to take a patient's vital signs, administer a medication, administer shots, perform venipunctures and taking a patient's intake history for their medical record. This training including the following:

1. Read about the patient's disease, disease diagnosis methods, disease treatments (medications, other therapeutic measures), potential side effects of medications and any treatments.
2. Verbally discuss with the nursing instructor the above in relation to the patient's presenting disease, as well as, concomitant illnesses and concomitant medications. This also included a requirement to understand drug-drug interactions as well.

3. Observing the performance of a therapeutic intervention, prior to performing my doing it alone (e.g. skin ulcer dressing changes, giving a shot etc.). I would have to explain, in detail, the rationale for the intervention, potential negative consequences if not performed correctly, any specific precautions to take, and a step-by-step description of the intervention I was being trained on.
4. Perform the nursing/therapeutic intervention with the nursing instructor observing me. The nursing instructor would document that I was 'qualified' to perform the specific therapeutic intervention independently.
5. Lastly, I had to pass the 'nursing board examination' to be a registered nurse and nurses are required to maintain their 'currency' with nursing and medical practice as evidenced with the continuing education requirement linked to nursing license renewal standards.

Therefore, clinical researchers need to be approaching clinical trials, and the care of our study participants, the 'subject', as equal to medical practice and ensure that professionals designated to 'care for our subjects', are trained to the same standards as non-clinical research subjects (e.g. medical practice, clinics etc). Would a physician/PhD/dentist/nurse practitioner in private practice actually delegate these responsibilities to un-qualified staff per state licensure requirements and professional liability standards? I believe not. As a professional who has held positions as a Research Nurse, Clinical Research Associate (CRA), Clinical Trial Manager, as well as in Clinical Compliance – Standards and Training, and Clinical Research Training, I continue to be concerned at the inadequate knowledge and lack of practical training (how are staff trained to obtain informed consent, identify and report AEs/SAEs, perform study procedures, review an Investigator's Brochure for safety profile review, documentation etc), for institutions, IRBs, investigators, sub-investigators, study coordinators and study personnel ranging from stand alone private practices to academic institutions.

In the training of our health care professionals, the educational approach includes self-study, classroom learning and on-the-job-training. However, with the emergence of on-line/e-learning/computer based training, many people believe that completion of such learning modules state that they are trained and qualified to conduct their role in clinical research. However, without the inclusion of on-the-job training, such on-line learning is merely the same as 'reading a textbook'. And, such a training practice for either a doctor or a nurse would not be viewed as resulting in a competent skill level for patient care (ie. qualified to care for the patient on the topic being 'read' online alone). As we move forward to guide the development of this regulatory requirement, I would like to strongly recommend that as the regulation is written, that OHRP take into consideration these requirements and most importantly 'on-the-job training' on specific topics and training documentation (i.e. training records) for deeming personnel 'qualified' to perform their assigned duties. (Wool, June 2008, *Monitor* magazine).

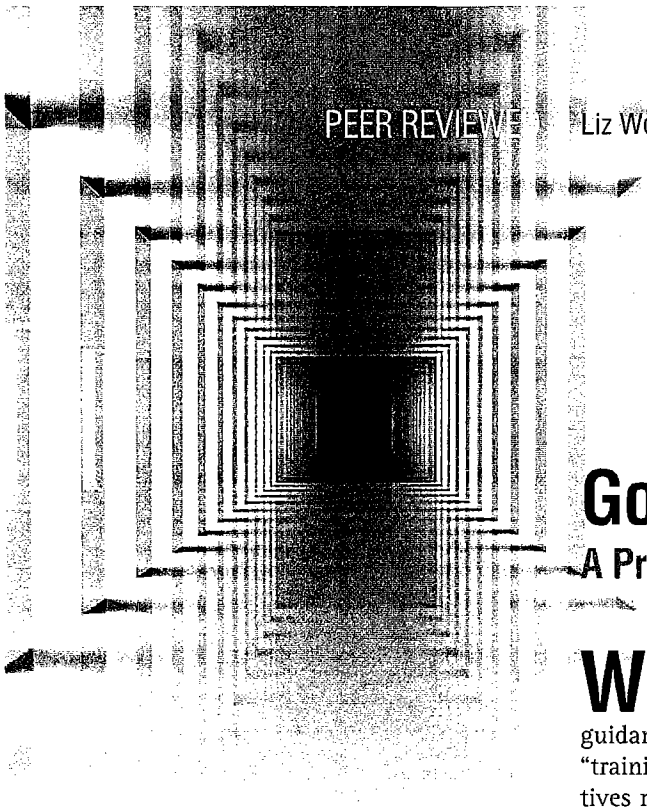
In closing, recommendations for training have been noted in the OHRP Determination Letters and FDA Warning Letters over the past few years (e.g. GCP, investigator responsibilities, adverse events, case histories, investigational product management and accountability, informed

consent, staff training on protocol/study procedures, corrective and preventive actions for errors in research execution etc.). Requiring mandatory training for institutions, investigators, IRBs and study staff engaged in clinical trials and under the purview of GCP can be substantiated and benchmarked to current requirements in the US CFR for GMP and GLP regulations as previously discussed. This level of regulatory requirement is needed as well in the GCP arena. Clinical researchers governed by GCP are actually 'closest' to the care of the study subject of all three of these specialties (GMP, GLP, GCP) so, why not then bring the training standards and requirements up to the same level as GLP and GMP?

I would be honored to be considered as a contributor to this regulation and the solutions for implementation 'in clinical research practice' as I am active in the clinical research industry (President, ACRP Northern California Chapter, DIA and SQA speaker, ACRP faculty, clinical research faculty positions at UC Berkeley, UC Santa Cruz, San Francisco State University, and program advisory board member UC Berkeley) and after 30 years in the healthcare profession and 18 years in clinical research, my passion is still strong to make a difference and be part of the solution!

Sincerely,

Liz Wool, RN, BSN, CCRA, CMT
President and CEO
QD-Quality and Training Solutions, Inc.



PEER REVIEWED

Liz Wool, RN, BSN, CCRA, CMT

Good Training Practice 101

A Primer for Employee Training Plans

This article describes the components of standardized employee training plans per job function/job title and the development of an individual employee's training plan.

What is good training practice? Although it may sound like something from a new U.S. Food and Drug Administration (FDA) regulation, guidance document, or regulatory guideline, it is not. In professional terms, "training" is a set of systematic processes designed to meet learning objectives related to a trainee's current or future job, and "good training practice" (GTP) is a term utilized when describing the standards to follow for training needs analysis, employee training plans (training curricula, individual training plans), task analysis, training curriculum development, instructional design (ADDIE [analysis, design, development, implementation, and evaluation]), training delivery methodology, instructional techniques, employee training documentation, waiver of an assigned training assignment, training documentation master files, methods and standards for training evaluation, and trainer qualifications. An integral component of GTP is the infrastructure standards associated with the implementation and management of these activities.

Comprehensive and relevant employee training requires an organized and methodically developed instructional plan complete with objectives, outlines, time frames, and a procedures manual. Without a formalized training plan, important details can be overlooked and consistency and uniformity will suffer.[1]

This article describes the components of standardized employee training plans per job function/job title and the development of an individual employee's training plan, which will support and document that you and your team (of employees and/or contractors/consultants) are qualified by education, training, and experience to perform your assigned job duties (21 CFR 312, 21 CFR 812, ICH E-6). This article also addresses employee training documentation, waiver of an assigned training assignment, and training delivery methodology items in a systematic manner to assist organizations that do and do not have in place standardized employee training plans. The other GTP topics mentioned earlier will not be covered here, as this article is a primer for the development of a standardized employee training plan. For those with more detailed training needs, a Selected Bibliography is provided for reference.

Employee Performance Improvement

Employee training and development focus is emerging, or has emerged, for many organizations in the form of a human performance improvement (HPI) model—a process whereby a variety of solutions are implemented to improve

performance in an organization.[2] HPI is systematic; it always follows a specific process for identifying business goals, diagnosing performance problems, recommending and implementing targeted solutions, managing workplace cultural issues, and evaluating the designated interventions' success.

When developing a standardized employee training plan, issues may arise with the organization or business that people may believe are related to employee training, but actually are not training issues; rather, they are organizational issues (i.e. lack of standards, lack of procedures, communication issues, etc.). These areas warrant further discussions with management to bring such assessments to their attention and to support the organization's overall effectiveness. In the HPI model, one of the primary goals is to link learning to individual performance and individual performance to organizational goals, objectives, and business results.

Organizations, departments, and managers need to identify the key performance indicators (KPIs), which are the expectations or requirements necessary for achieving the overall results of most importance to the organization, as well as for each specific job function/position. Identifying KPIs requires evaluating the business and the inherent factors that are vital for the organization to meet its business goals. KPIs align with the organizational values and goals, and may be categorized under the headings of job knowledge, quality, productivity, initiative, teamwork, customer focus (internal and external clients), communication skills, and planning and organizing work. For supervisors and management, additional KPIs may also include leadership, delegating, managing, and development of employees.[3] Those measuring performance should first look at the desired condition, then identify and measure the accomplishments that contribute to reaching it, and then analyze the behaviors that contribute to the accomplishments.[4]

It takes TIME to implement a performance model in an organization. A useful system diagnostic method is the evaluation of TIME: training, incentives, motivation, and environment.[5] The TIME method is used to assess and diagnose problems with employee performance and work product, the work environment, and the organizational structures and systems that either support or hinder job performance.[5] If one TIME component fails, the entire performance system becomes unstable.[5] This is an important area for evaluation to ensure maximum success and employees' engagement in both the organization and in their own training and development.

A useful system diagnostic method is the evaluation of TIME: training, incentives, motivation, and environment.

Clinical research goals and performance are measured by ensuring human subject protection while studying and evaluating new products and therapies for humankind. All employees, regardless of their titles or functions, contribute to this mission. Due to the space allotted for this article, the details of performance management (organization, department and job function levels, performance technology/consulting), KPIs, and TIME factors—all crucial components of organizational and employee effectiveness—will not be addressed. Rather, this information is contained in the Selected Bibliography at the end.

Establishing Performance-Competency Standards

Approximately 90% of an employee's workplace skills and knowledge are learned through on-the-job training[6] through either a "buddy system," which has the potential for perpetuating incorrect procedures, practices, decision making, shortcuts, mistakes, confusion, and inconsistencies in job performance passed from one employee to another, or through structured on-the-job training, which has predefined standards for performance and competency requirements. "Competency" denotes that the employee is properly qualified to perform a specific task. The use of a competency-based approach to training has the advantage of communicating a common set of performance expectations.[7]

Employees need to be qualified (able to perform the job as required) to perform a job task/activity upon training completion through the achievement of a competent level of performance, as exhibited in the correct application of the knowledge, skills, and behaviors for their position (job). Therefore, the clinical research industry needs to establish performance-based standards. This methodology requires employees to practice their new skills/knowledge/behaviors and provides an opportunity for them to confirm their correct understanding of the skill according to the associated performance standards. As employees practice the skills with their assigned trainer, they receive immediate feedback on their performance.

Our colleagues in the good manufacturing practice (GMP) and good laboratory practice (GLP) fields are required to have a standardized employee training plan for each job function/job title and training documentation in place.[8] The good clinical practice (GCP) field, however, does not specifically require implementation of employee training plan standards.[9] This trend is changing now, with the European Union GCP Inspectorate focus on the standards, systems, and processes that are in place for employee training.

Similarly, the FDA has noted inadequate training in its investigator/sponsor FDA Warning Letters[10-12] and requested that warning letter responses contain a detailed outline of procedures or processes that would be implemented to prevent the future occurrence of inspection observations, including staff training. In May 2007, an FDA Draft Guidance on *Protecting the Rights, Safety, and Welfare of*

Study Subjects–Supervisory Responsibilities of Investigators was published in the *Federal Register.* It also addresses training requirements and standards at the site level, under the purview of the investigator. This document outlines appropriate delegation of study-related tasks that are clinical or medical in nature, such as evaluating study subjects to assess clinical response to the investigational therapy (e.g., global assessment scales, vital signs, or providing part of the medical care provided to subjects during the course of the study). It notes: "Most clinical/medical tasks require formal medical training and may also have licensing or certification requirements." The guidance document further describes standards for adequate training at the site (protocol, study, delegated tasks, regulatory requirements [conduct of clinical trials and human subject protection], etc.), and states that "staff are competent to perform the task that they are delegated."

Therefore, investigational sites, sponsors, and contract research organization (CROs) need to ensure that they have standardized employee training plans in place to document that their staff are qualified to perform their assigned job duties. In line with this approach of standardized employee training plans, Silver and coauthors, in their article, "A Professional Development Model in Clinical Research for Developing Countries," described an employee training and capacity-building model for clinical research staff in South Africa, which was developed by the Aeras Global TB Vaccine Foundation and the South African Tuberculosis Vaccine Initiative.[13]

Developing a Standardized Employee Training Plan

Before compiling the employee training plan, the KPIs for the organization, for its departments, and for each job function/title must be collected and understood. In addition, the organization must be researched–its companies and departments, and the other departments, vendors, and business partners with which it works in its area of specialty.

The next step is to review the company and department organizational charts and identify the assigned work duties for each job function and who the employees interface with on a routine basis, as well as the job descriptions (which must be written and current); these will serve as the primary reference in standardized employee training plan development. Review of the job descriptions should begin by an analysis of the knowledge, skills, behaviors, and tasks that the employees are required to exhibit or perform.

An integral component of developing a standardized employee training plan is to conduct interviews with management, employees, peers, business partners, vendors, and other individuals/departments in order to understand the full scope of the job function/title, which may not be transparent when speaking with one of these groups individually.[4] Furthermore, this facilitates assessment and understanding of how each department interfaces and works with these groups, and whether each department "delivers" any work product (materials prepared by an employee) to these groups or "receives" work products from others.

If a group delivers any work product to other groups, of course, the employees must be trained on the standards and what a "quality work product" standard is upon delivery to another group or customer. Additionally, they must learn and understand "what is done well" and "what needs improvement" (the performance gaps) regarding competency in performing their job duties. This information will assist in identifying items to be included in the standardized employee training plan and the associated performance standards, which will ensure a comprehensive, global approach to the employee training plan, whether it is related to technical skills or to professional development.

Finally, the mandatory training requirements should be identified at both the company (corporate) level and at the department level. This information will be included in each job function/job title training plan, and subsequently in each employee's training plan (see Figure 1).

Knowledge, Skills, and Behaviors

In evaluating the job description, the focus must be on knowledge, skills, and behaviors, extracting these requirements as the basic structure for the standardized employee training plan.

"Knowledge" means that the employee possesses a confident understanding of a subject with the ability to use this understanding for a specific task. In our profession's terms, "knowledge" is an understanding of the regulations, guidelines, standards, standard operating procedures (SOPs), and best practices in clinical research for a specific job duty/assignment. For example,

Figure 1 Overview. Standardized Employee Training Plan