

Creating a Comprehensive Training Documentation Program

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The regulations mandate that individuals involved in research animal care and use receive adequate training, but they fail to address the documentation of the training. The authors provide guidelines for training documentation and, as an example, describe the program in place at the University of Pennsylvania.

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As members of the laboratory animal science community, we are acutely aware of the need to provide accurate and adequate training to animal facility personnel. With the training of staff members, we improve the quality of research and animal welfare. Although many laboratory animal science regulatory bodies require training and several resources exist for training materials within the research community, there has been little effort to formally address the documentation of the training.

For example, the *Guide for the Care and Use of Laboratory Animals* states: "... AWRs and the PHS *Policy* require institutions to ensure that people caring for or using animals are qualified to do so ...", and "Personnel caring for animals should be appropriately trained ...¹". The *Education and Training in the Care and Use of Laboratory Animals* states: "... Regulations that implement the Animal Welfare Act specifically require that institutions provide training ...²". However, these regulations do not provide a standard outline for maintenance of training documentation³.

When asked about what should be included in a facility's training documentation program at an IACUC 101 session, representatives from the Public Health Service, the United States Department of Agriculture (USDA), and Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC), International, responded that they had no particular requirements for a training program, except that the training and documentation program should be consistent throughout an institution and should document all relevant material⁴.

The Federal Drug Administration's (FDA) Good Laboratory Practice (GLP) regulations covering preclinical testing of pharmaceuticals and medical devices present a more comprehensive view of what to

document while still leaving the details to the institution. The regulations state: "... Each individual engaged in the conduct of or responsible for the supervision of a nonclinical laboratory study shall have education, training, and experience, or combination thereof, to enable that individual to perform the assigned functions. Each testing facility shall maintain a current summary of training and experience and job description for each individual engaged in or supervising the conduct of a nonclinical laboratory study ...⁵".

Other international regulatory bodies, including the Organisation for Economic Co-operation and Development (OECD) and AAALAC, International, have guidelines requiring training for the individuals working with research animals, but again, do not impart specific details with respect to training documentation^{6,7}.

In essence, to demonstrate compliance with the various regulations and guidelines, a facility must document not only its training program but also the experience that personnel have acquired before accepting their current position in any external training programs. Additionally, training documentation allows IACUCs to effectively monitor animal care and use programs^{3,8,9}; meet continuing education requirements for laboratory animal technicians; help with employee performance reviews; meet the expectations of client or other audits (for contract labs or other similar organizations), regulatory inspectors, and organizational management; help justify a training budget; and help the facility if legal situations involving training and/or animal use arise. As a special note to those in industry or contract laboratory situations, the need to demonstrate adequate and even above-average training is a necessity during client audits. Clients will frequently base a decision on placing busi-

ness with a specific facility in part on employee training as demonstrated by the facility's training documentation system. Maintaining a well-organized and easily accessible system can facilitate such reviews of employee training records and create a favorable impression on the auditors.

Basic areas to cover when creating a training documentation system or evaluating an existing one for improvement include determining which staff positions require training documentation, what system will be employed to document the training, who will maintain the documentation, and who will have access to the records. From a legal standpoint, all staff positions should have training documentation requirements. There should be a definition of the level of documentation for each job type.

Positions

Kennedy identifies some employee positions that should have their training documented¹⁰. These positions include animal care providers, research and veterinary technicians, students with animal contact, interns, summer or part-time students³, post-doctorates, visiting scientists³, IACUC members¹¹, administrative staff, and physical plant personnel¹⁰. Additionally, documentation should include veterinarians, Principal Investigators (PIs)³, quality assurance personnel, and regulatory affairs personnel staff.

Programs

The obvious answer is to document current activities. However, to be as comprehensive as possible, a training program should incorporate other references and ideas in the field. For example, GLP training documentation includes the prior experience of the individual. To have a meaningful standard, training documentation would need to start before a person is hired. This standard would include documenting degrees or college transcripts, certifications, resumes/curricula vitae, veterinary or animal health/veterinary technician licenses, USDA accreditation for veterinarians, and Drug Enforcement Agency (DEA) registra-

tions. A security program should include verification of some or all of these items. Furthermore, any documentation program should consider any research awareness or public relations training.

An overall training program would include documentation of the following subjects:

- Core laboratory animal modules for technical and nontechnical staff
- Company/facility policies and procedures
- Orientation programs
- Facility tours
- IACUC training³
- Retraining³
- In-house certifications
- Species-specific and procedure-specific training¹²
- GLP training
- Other regulatory training (*e.g.*, International Organization of Standards)
- Standard Operating Procedure training
- Occupational safety and health training, along with other safety training, such as equipment and radiation training¹³
- Ongoing external continuing education—for example, American Association for Laboratory Animal Science (AALAS) seminars, research-related sources
- Training materials read during the course of employment
- Data handling
- Project-specific training
- Buddy or one-on-one training
- Bilingual training

Details to be included for didactic and other training include the title of the course³, date(s) given³, duration, outline and/or course abstract, mode of delivery, instructors' names³, instructors' qualifications, employee name³, employee department³, employee identification number (if applicable)³, and acknowledgment by the employee and employee's supervisor of training attendance. Standard classroom

training courses should provide a sign-in sheet or other acknowledgment of training with a signature of the employee.

Documentation Systems and Maintenance

The process of documenting and maintaining the records is again specific to an institution. Smaller institutions may find that maintaining paper records with a standard training program check-off list and attendance records in a file for each employee is sufficient. However, larger institutions with multiple locations and a combination of formal class, informal one-on-one, and online training programs may find computer-based systems, either purchased or developed in-house, easier to manage. In-house systems typically use database management or spreadsheet programs. An important decision with the implementation of any type of system is the determination of who will maintain and update the system. A Training Coordinator (TC) usually assumes those responsibilities¹⁰. In the absence of a TC, other departments or individuals can successfully maintain the records. These positions include the IACUC members (Chair, Coordinator, other members), Human Resources, Regulatory Affairs/Quality Assurance, Supervisors, Safety Officers, employees, and others. Again, larger institutions will often have different departments administer parts of their training programs and maintain the actual documentation. Ideally, a complete documentation of an employee's entire training record should be in a central location. The system should have all records easily accessible on demand to accommodate unannounced regulatory inspections. As previously discussed, the system should maintain a consistent format throughout the institution⁴.

Documentation Access

Because an employee's training record contains specific information related to job performance, an institution should keep the record in a secure location with limited access. An institution should implement a system to determine who has access to the

Summary of Training Documentation at the University of Pennsylvania

The University of Pennsylvania is a large academic institution with an affiliated medical school, veterinary school, and dental school, to all of which the animal care and use program applies. Over the past several years the institution has developed and implemented many additional formal training programs to meet the mandatory training requirements. I will outline the means by which we currently document training and touch on the future of our documentation.

To better visualize the scope of what we are documenting with regard to training, I will briefly overview the University of Pennsylvania's Training Program related to animal use. Staff members receiving training include 120 animal care providers, 14 clinical workers, 3,700 research faculty and staff members, 200 physical plant employees, and 25 IACUC members. Animal care providers complete on-the-job training specific to their task and attend mandatory core training modules and continuing education classes. AALAS certification is desirable but is not a requirement. New PIs and their staff must complete a web-based training module orienting them to research, a species-specific hands-on training course, special procedures training (if needed) and a 'facility tour' of the animal area they will be using. Physical plant employees attend annual training on the proper procedures for entering animal areas. The Environmental Health and Radiation Safety (EHRS) Department trains all groups with reference to their specific tasks, as required by OSHA. Some of these modules include 'Laboratory Safety', 'Occupational Exposure to Bloodborne Pathogens', and 'Radiation Safety Training'.

There are three departments enforcing different training programs to fulfill federal, state, local, institutional, and departmentally mandated rules and regulations. These departments are the University Laboratory Animal Resources (ULAR), the IACUC, and the EHRS. Each department documents and maintains its own program records. These three departments are physically located 5–10 blocks from each other.

Several systems and maintenance strategies for training records are in place at Penn. The ULAR presents the 'facility tour' training, which the research faculty and staff complete. Protocols using biohazardous agents require an additional presentation to be given by the research group to the animal care staff. Completion of these training events allows access to the facility by the PI and his/her staff. The ULAR TC maintains records on all training attended by animal care staff, recording training on paper and electronically. A Microsoft Excel spreadsheet allows the recording of dates of training classes offered, topics covered, and list of attendees. A master binder consisting of a section for each individual staff member contains hard copies of 'checklists' signed by the trainee confirming that he/she has received training on a particular subject. An additional binder includes detailed information on each training session offered as well as the hard copy of the sign-in sheet. The ULAR TC maintains records in the same format of the training for physical plant employees in regard to entering animal facilities. Individual supervisors receive copies to keep in employee files.

The Office of Regulatory Affairs (ORA) maintains training records for the online training and the species-specific hands-on training as required by the IACUC. This office records all training completed on a Microsoft Excel spreadsheet. Both the IACUC and ULAR have access to and can manipulate this spreadsheet. The ULAR office keeps on file hard copies of attendance and procedures completed in species-specific labs. Attendees keep a 'checklist' of procedures completed, signed by the instructor and the student. They also receive a certificate of successful completion for their files.

The EHRS Department maintains records for all EHRS-required training for all university personnel. A master database contains entries on all attendees who have completed training. This department reviews all animal use protocols with potential biohazards or other EHRS issues to verify that training has been completed before full protocol approval is granted.

The future of training documentation at Penn needs to include an integrated database wherein the three departments can easily verify training records and enter information. Time spent verifying training can delay protocol approval. At present, it is necessary to spend additional time entering personal information into different records and databases. In progress is the integration of ULAR's electronic training documents into a database. A well-developed database will improve the accessibility and organization of our training records. ULAR is currently evaluating computer software systems to integrate protocols, contact information, animal ordering, receiving, census, billing, clinical care, cost accounting, and training. Many integrated database systems allow easy importation from existing user-created databases. I am hopeful that when an integrated computer software program is identified and implemented, the three departments—ULAR, ORA, and EHRS—will be able to share training information efficiently and effectively.

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information, with the employee knowing who is able to view the training record. Not only is this considerate, but it also serves to ensure the accuracy of an employee's records, which may be helpful for possible legal situations. Individuals who would have access to the information would include IACUC members, Human Resources staff, managers and supervisors,

attorneys, the FDA, the USDA, Occupational Safety and Health Administration (OSHA), clients, and other inspectors.

Employers should keep employee health-related information separate from training records. Various laws and regulations stipulate that such health-related information is confidential (R. Matsson,

Joslin Diabetes Center, personal communication).

Training Effectiveness

As the *Education and Training in the Care and Use of Laboratory Animals* points out, it is essential also to document the effectiveness of the training program². Assessing the effectiveness of the training aims to ensure the competence of the individuals who received this training. Comprehensive methods to document the effectiveness of a training program may include quizzes and examinations³, progression in AALAS certification by employees, auditing by outside and/or compliance groups¹³, and monitoring for trends and deficiencies in employee performance. For occupational health and safety programs, records of trends in illness and injury can provide the trainers with feedback as to the effectiveness of their programs¹³. This allows the employees to express their feelings about the program to provide employers and trainers with guidance for future training². Although informal verbal feedback should always be appreciated and encouraged, surveys will usually suffice^{2,13}.

Furthermore, employees should never feel that they are being forced to sign off on their training. They should always feel that they have been sufficiently and effectively trained. Therefore, employees should have the option of deciding whether and when they are ready to sign the training documentation or whether they need additional training to comprehend the material fully.

Conclusions

There are several reasons to document training, including regulatory oversight, IACUC or managerial mandates, and business concerns. Although training documentation is required, individual institutions can determine the details on their own. A thorough examination of the regulations as well as other aspects of a training program can ensure that documentation is adequate and will help a facility maintain a high level of quality in research and animal welfare.

The institution that answers and addresses the basic questions about training documentation can expect to have a successful, established training program in the long run.

Received 12/11/03; accepted 1/7/04.

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