

18-106 Review of Training and Education Keeling Center for Comparative Medicine and Research Department of Veterinary Sciences

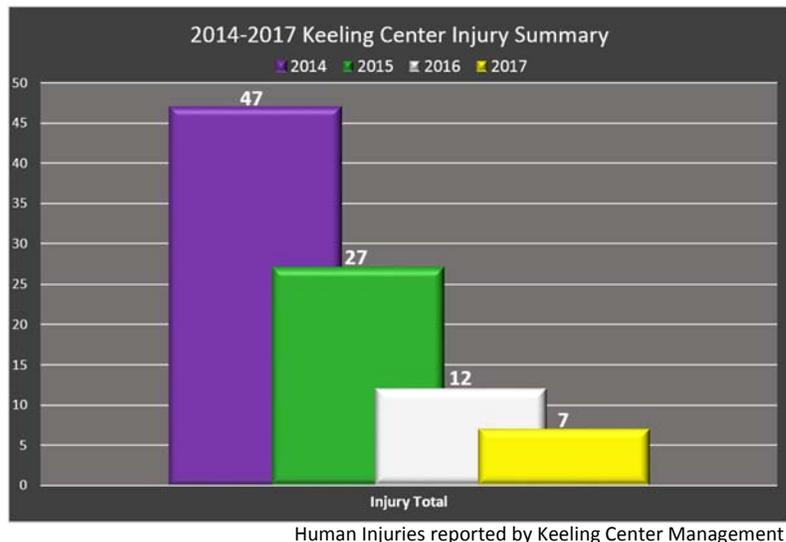
EXECUTIVE SUMMARY

The Keeling Center for Comparative Medicine and Research (the Center) located in Bastrop, Texas, employs 148 employees and provides research and laboratory support for MD Anderson and other external research communities. Research projects at the Center cover subject areas such as HIV, Zika Virus, monoclonal antibody therapies, autoimmune disease and cancer. The facility currently houses 129 chimpanzees; 883 rhesus, 640 squirrel, and 325 owl monkeys; and 200 baboons.

The objective of this audit was to determine if education and training was provided to ensure the safety of humans and primates at the Center. Generally, we concluded that management has established requirements for, and provided employees with education and training with some improvements needed, as outlined in Observation #1.

Management continues to enhance various safety measures to protect employees and primates at the Center as evidenced by the following:

- Over the last four years employee injuries decreased by 85% due to efforts of the Center's Management and Environment Health and Safety(EHS). Management monitors trends related to employee injuries and collaborates with relevant departments to minimize subsequent occurrences.
- The Quality Assurance Unit performs periodic reviews of Good Laboratory Practices (GLP) studies including training requirements.
- Security enhancements have been implemented in the chimpanzee area/enclosures to mitigate occurrences of adverse events.
- Regulatory agencies perform periodic reviews of animal welfare and safety at the Center.
- A Training and Steering Committee, established in 2016, has undertaken several initiatives to create a more efficient and compliant training program for all employees.



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While efforts have been made to improve safety, there are opportunities for improvement related to training and education in the following areas:

- Monitoring to ensure compliance with training guidelines and procedures
- Improving documentation supporting reviews
- Reviewing and updating training guidelines, and
- Formalizing requirements and documentation for employee re-education

Management Summary Response:

Management agrees with the observations and recommendations and has developed action plans to be implemented on or before December 2018.

Appendix A outlines the methodology for this project.

The courtesy and cooperation extended by the personnel at the Center is sincerely appreciated.

Sherri Magnus

Sherri Magnus, CPA, CIA, CFE, CRMA
Vice President & Chief Audit Officer
February 21, 2018

DETAILED OBSERVATIONS

Observation 1: Monitor to Ensure Compliance with Training Guidelines and Procedures

Ranking: Medium

The Center has established a robust set of standard operating procedures including training requirements. However, management is not consistently monitoring compliance with these standards. Our testing identified instances of non-compliance with these requirements.

Based on a review of twenty-six judgmentally selected employee training records, the following instances of noncompliance were identified:

- While all employees received Chimpanzee Security and Recovery training in the past, twenty-one employees (81%) did not consistently receive the training annually as outlined in the Standard Operating Procedure (SOP). According to management, training has not occurred because the SOP is under revision.
- Two employees did not receive required Zoonotics¹ training. Additionally, two employees did not receive the training annually as required by the Center's training guideline matrix.

Recommendation:

Management should monitor employee training records to ensure timely completion of required training outlined in SOP's and/or training guidelines.

Management's Action Plan:

SOP AC.115.xx (Chimpanzee Security and Recovery) has been revised to clarify that annual training is only required for key personnel directly involved with chimpanzee recovery activities. The SOP is currently being distributed for signatures and once approved, will be provided for training. Once training is complete, a copy of the SOP and applicable training records will be provided.

All new Keeling Center for Comparative Medicine and Research (KCCMR) personnel will continue to receive training on SOP AC.115.xx during orientation. Due to significant procedural revisions, all KCCMR personnel will be required to obtain training on this new revision of SOP AC.115.xx (Chimpanzee Security and Recovery) per SOP GP.002.xx (Training and Training Records).

¹ Zoonotics is an infection which originates in animals that can cause serious diseases in humans.

DETAILED OBSERVATIONS

- Two employees did not receive required Hazcom/BBP² training. Additionally, one employee did not receive the training annually as required by the Center's training guideline matrix.
- One administrative employee had not completed the required Safety in Laboratory training. However, the training was subsequently completed before the close of this review.

When required training is not received, risks such as severe injury or death of humans and/or primates, damage to the institution's reputation and possible sanctions imposed by external agencies may occur.

In addition, key personnel involved with chimpanzee recovery activities will be required to obtain training on an annual basis.

In addition, the Department of Veterinary Sciences (DVS) Training Guidelines document is under revision to include Chimpanzee Safety Training and will be provided when complete.

We are revisiting the Training Database to ensure that all departmental trainings (e.g., Zoonotic Exposure Risk, HazCom/BPP, etc.) are entered and reviewed with the system ultimately providing alerts to immediate supervisors for any missed or past due trainings. Additionally, SOP QA.056.xx (Quality Assurance Unit Procedures) will be revised to indicate that the QAU will provide additional training compliance support (e.g., review of the GLP Training Files for SOP review and/or training and review of the training database for training guideline compliance, etc.) by implementing a formal inspection process.

² Hazard Communication and Blood-borne pathogens training educates employees about hazards in the work environment such as chemicals and biohazards.

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DETAILED OBSERVATIONS

The inspection processes will be appropriately documented and presented to Management in a QA Inspection Report.

For audited files that have been identified as missing trainings during this internal audit process, a Note to File (NTF) will be included in each identified employee file indicating the missing training details. Copies of each NTF will be provided upon completion.

Responsible Executive:
Dr. Christian Abee
Owner: Robert Orozco
Due Date: 06 Apr 2018

Observation 2: Improve Documentation of Training Reviews

Ranking: Medium

Based on a review of employee training records, the following observations were made:

- No evidence of annual supervisor reviews of non-GLP or GLP training records as required by the Training and Training Records SOP. During interviews, supervisors attested to reviewing the training records but the reviews are not formally documented.

Recommendation:
 Management should improve the documentation of reviews by the following:

- Establish a process to formally document supervisor annual reviews of employee training required by the Training and Training Records SOP.

Management's Action Plan:
SOP GP.002.xx (Training and Training Records) will be revised to require supervisors to document their review, via training database or training file, of all required trainings for their respective direct reports during their annual performance evaluation. Once SOP revision is complete, a copy of the SOP will be provided.

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DETAILED OBSERVATIONS

- The 2016 audit of GLP training records performed by the Research Regulations Specialist was not sufficiently documented. Specifically details such as identified discrepancies, required corrective actions and final resolution of applicable instances of non-compliance were not included.

Without formal evidence to support independent reviews, there is an increased risk that reviews are not performed or performed as intended. Non-compliance may not be detected and activities may not be performed according to management's expectations.

- Establish documentation requirements for audits performed by the Research Regulations Specialist to ensure adequate detail is documented. Relevant policies and procedures should be updated to include documentation requirements for these reviews.

Compliance of this requirement will be monitored via an inspection by the QAU (see Observation #1 details).

The Research Regulations Specialist GLP SOP Training audit will become an official QAU inspection process. SOP QA.056.xx (Quality Assurance Unit Procedures) and GP.002.xx (Training and Training Records) will be revised to indicate that the QAU will provide review of the GLP Training Files for SOP training and/or review and the training database for training guideline compliance. This inspection process will be presented to Management in a QA Inspection Report. Once SOP revision is complete, a copy of the SOP will be provided.

Responsible Executive:

Dr. Christian Abee

Owner: Robert Orozco

Due Date:

- April 6, 2018 (for SOP revisions and initial Training records inspection)
- December 3, 2018 (QA inspection completion after next annual performance evaluation period for training documentation supervisory review)

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DETAILED OBSERVATIONS

Observation 3: Review and Update Training Guidelines

Ranking: Low

The training guideline matrix is not current. For example, it does not contain the annual requirement for Chimpanzee Recovery and Safety Training. Also, while certain employees (Non-GLP) are exempt from taking Good Laboratory Practice (GLP) training, the matrix indicates that it is required.

When training guidelines are not periodically reviewed and updated, there is an increased risk of noncompliance with regulations and internal procedures. In addition, there is an increased risk of injury or death if new emerging risks are not periodically evaluated.

Recommendation:

Management should update the Center's training guideline matrix to include required Chimpanzee Recovery and Safety training and the exemption of Non-GLP employees from taking GLP training.

Management's Action Plan:

The DVS Training Guidelines document has been revised to include Chimpanzee Safety Training and the removal of the GLP training requirement, which is exclusively maintained through the QAU Training Program for GLP study personnel via SOP QA.054.xx (GLP Compliance Training Program). Additionally, this document will only be applicable to the DVS department as DVS has no mechanism to monitor training compliance of other departments. A copy of the revised document will be provided when complete.

Responsible Executive:

Dr. Christian Abee

Owner: Robert Orozco

Due Date: April 6, 2018

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DETAILED OBSERVATIONS

Observation 4: Formalize Requirements and Documentation for Employee Re-education

Ranking: Low

When an incident occurs where an employee or primate is injured, re-education may be performed dependent on the nature and severity of the incident.

Based on a review of employee injuries investigated by Environment Health and Safety (EHS), some of the action plans warranted employee re-education. However, the re-education provided was not formally documented in the training records.

When re-education is not documented, there is limited assurance that the re-education occurred which may lead to re-occurrence.

Recommendation:

Management should establish a process to document employee re-education when management has determined that re-education is warranted following significant incidents and/or adverse events.

Management's Action Plan:

Following occurrences of significant events requiring an accident investigation, EHS will document and track all required recommendations and/or corrective actions using the current accident investigation software. The automated workflows are scheduled for implementation by September 1, 2018. Additionally, any incident and/or adverse event occurrence that includes an animal or employee requiring a revision to an SOP and/or Policy, training or re-education will be required and appropriately documented through the KCCMR Controlled Document Process [i.e., SOPs GP.001.xx (Developing Standard Operating Procedures [SOP] and Policies) and GP.002.xx (Training and Training Records)].

Responsible Executive:

Dr. Christian Abee

Owner: Robert Orozco

Due Date:

- KCCMR process is currently in place
- 01 Sep 2018 (EHS implementation of automated workflows)

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Appendix A**Objective, Scope and Methodology:**

The objective of this audit was to determine if education and training was provided to ensure the safety of humans and primates at the Keeling Center for Comparative Medicine and Research (Bastrop Facility). This included a review of education provided subsequent to incidents where a primate or human was injured. The review covered the period of September 1, 2016 through December 2017 and any related periods.

Our procedures included the following:

- Interviewed key personnel within the Center, Environmental Health & Safety, Employee Health & Well Being and Office of Research Oversight and Integrity, to gain an understanding of processes relating to training and reporting significant incidents and adverse events.
- Reviewed relevant Federal regulations, and institutional policies and procedures.
- Reviewed results of periodic reviews conducted by external regulatory agencies, Institutional Animal Care and Use Committee (IACUC), Training and Steering Committee, quality assurance unit, supervisors and the Center's regulation specialist.
- Reviewed training and education for a sample of employees to ensure required training was completed timely.
- Reviewed a sample of reported incidents and related supporting documentation including subsequent training relating to human and non-human primates.

Our internal audit was conducted in accordance with the *International Standards for the Professional Practice of Internal Auditing*.

Number of Priority Findings to be monitored by UT System: None

A Priority Finding is defined as “an issue identified by an internal audit that, if not addressed timely, could directly impact achievement of a strategic or important operational objective of a UT institution or the UT System as a whole.”