

January 15, 2019

DEPARTMENT OF HEALTH & HUMAN SERVICES

FOR US POSTAL SERVICE DELIVERY: Office of Laboratory Animal Welfare 6700B Rockledge Drive, Suite 2500, MSC 6910 Bethesda, Maryland 20892-6910 Home Page: http://grants.nih.gov/grants/olaw/olaw.htm PUBLIC HEALTH SERVICE NATIONAL INSTITUTES OF HEALTH

FOR EXPRESS MAIL:

Bethesda, Maryland 20817

Telephone: (301) 496-7163 Facsimile: (301) 402-7065

Office of Laboratory Animal Welfare

6700B Rockledge Drive, Suite 2500

Re: Animal Welfare Assurance A3222-01 [OLAW Case R]

Aleister Saunders, Ph.D. Senior Vice Provost for Research Drexel University 3180 Chestnut Street, (b) (4)

Philadelphia, PA 19104

Dear Dr. Saunders,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your December 12, 2018 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Drexel University, following up on an initial telephone report on November 19, 2018. According to the information provided, OLAW understands that in two different rodent survival surgeries, aseptic technique was not used. In a rat craniotomy, the surgeon did not wear a surgical mask, used nonsterile gloves and did not change them between procedures, and did not sterilize instruments between animals and put the instruments on a non-sterile surface. In a mouse craniotomy, the surgeon used nonsterile gloves and cleaned the surgical site using only one swipe of an alcohol pad.

The corrective actions consisted of retraining the laboratory staff, conducting post-approval monitoring of these laboratories and directly observing surgeries, amending the surgery policy to describe appropriate preparation of the surgical site, and reminding all animal users about the requirement for using aseptic technique and following institutional policies.

Based on its assessment of this explanation, OLAW understands that measures have been implemented to prevent recurrence of this problem. OLAW concurs with the actions taken by the institution to comply with the PHS Policy.

Sincerely,

(b) (6)

Axel Wolff, M.S., D.V.M. Deputy Director Office of Laboratory Animal Welfare

cc: IACUC Chair



December 12, 2018

Axel Wolff, DVM Director, Division of Compliance Oversight Office of Laboratory Animal Welfare National Institutes of Health Rockledge 1, Suite 360 6705 Rockledge Drive Bethesda, MD 20892

Dear Dr. Wolff:

Drexel University, in accordance with Assurance D16-00138 and PHS Policy IV.F.3., provides this report of noncompliance where aseptic technique was not followed during rodent survival surgery. The work performed on this protocol is supported by NIH grant award number 5R01MH85666.

During the 2018 AAALAC site visit, failure to adhere to aseptic technique as required in the approved IACUC protocol and the Drexel IACUC policy for surgery and care for rodents was observed during two survival surgical procedures. One of the surgical procedures was supported with NIH funding.

- While performing craniotomy surgery on young rats, the surgeon was not wearing a surgical mask, conducted surgery with non-sterile nitrile gloves, utilized the same surgical instruments for up to 4 separate surgeries without using the hot bead sterilizer between surgeries, placed surgical instruments on a not sterile surface, and did not change surgical gloves after handling animal for surgical prep and recovery and before conducting surgery.
- While conducting craniotomy surgery on mice, the surgeon conducted surgery with nonsterile nitrile gloves and prepped the surgical site with a single swipe of an alcohol pad.

On 11/14/2018, the IACUC met for a regularly convened meeting and discussed the findings. The IACUC voted to approve the following plan of action:

• The IACUC Chair will notify those non-compliant laboratories that all staff which perform surgery must attend a surgical training session conducted by a qualified Office of Research staff member within two weeks of the date of notification or as otherwise determined by the IACUC chair.

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IACUC@drexel.edu | drexel.edu/research



- The Animal Welfare Analyst will observe surgical procedures as a routine component of the post approval monitoring program. Re-training and educational sessions will occur as necessary.
- The current IACUC policy referencing rodent surgery will be modified to include a statement that the surgical area must be scrubbed in a circular outward path from the intended incision site three times alternating between alcohol and betadine or other skin disinfectant.
- The IACUC chair will send a reminder to all animal users regarding the importance of aseptic technique when conducting surgery and adherence to approved IACUC protocols and policies.

Drexel University is committed to protecting the welfare of animals used in research and appreciates the guidance and assistance provided by OLAW in this regard. Should you have any questions regarding this report, please contact Michael O'Connor, MD, PhD, IACUC Chair or Richard Huneke, DVM, attending veterinarian.

Thank you for your consideration of this matter.

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Aleister Saunders, Ph.D.) Senior Vice Provost for Research Institutional Official

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Morse, Brent (NIH/OD) [E]

From:	OLAW Division of Compliance Oversight (NIH/OD)
Sent:	Monday, January 14, 2019 5:07 PM
То:	Iacuc; OLAW Division of Compliance Oversight (NIH/OD)
Cc:	^{(b) (6)} Saunders, Aleister
Subject:	RE: Reports of Non-Compliance, Adverse Event - Drexel University- D16-00138

Thank you for submitting these reports. We will send official responses soon.

Best regards, Brent Morse

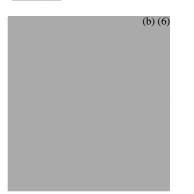
Brent C. Morse, DVM, DACLAM Division of Compliance Oversight Office of Laboratory Animal Welfare National Institutes of Health

From: lacuc <iacuc@drexel.edu> Sent: Monday, January 14, 2019 3:43 PM To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov> Cc: (b) (6) Saunders, Aleister <ajs56@drexel.edu> Subject: Reports of Non-Compliance, Adverse Event - Drexel University- D16-00138

Good Afternoon,

Please find attached two final reports of noncompliance and one final adverse event report to the Office of Laboratory Welfare. Initial reports were made by phone on 11/19. Please let me know if you need any additional information.

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To: Aleister J. Saunders, Institutional Official

From: Michael O'Connor, Chair, IACUC

Re: Report of the Institutional Animal Care and Use Committee: Program Review and Inspection of Animal Facilities and Laboratories, Fall 2018

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The Institutional Animal Care and Use Committee (IACUC) is required to perform inspections of all animal use areas semiannually. To meet this mandate, teams consisting of at least two (2) IACUC members were formed to inspect both the University Laboratory Animal Resource (ULAR) facilities and individual laboratories where animal work is performed outside of ULAR facilities. All IACUC members were invited to participate. The inspection included all three Drexel University campuses: Queen Lane (10/18/2018), Center City (10/22/2018), and University City (10/25/2018).

At the time of the inspection, the inspectors discussed the deficiencies with the investigators or their representatives (if present), and provided a plan and the date by which to rectify the problem. All investigators visited were notified in writing regarding the outcome of their inspection with either a "Deficiency" or "Gold Star" email. Recommendations included any items found on inspections that could be improved, but are not necessarily a deviation from a regulation or an institutional guideline.

Deficiencies are denoted as Significant or Minor. A **Significant Deficiency**, as defined in the PHS Policy and the USDA Animal Welfare Regulations, refers to any facility or program deficiency that is or may be a threat to the health or safety of animals. Significant Deficiency was also assigned to all instances where expired anesthetics, analgesics and euthanasia drugs were found in the lab and not stored and labeled appropriately to avoid their use in animals. A **Minor Deficiency** includes findings in which immediate solutions generally are not necessary to protect life or prevent distress.

The IACUC is also required to review the institution's Animal Care and Use Program semiannually. The review was completed by a subcommittee of the IACUC which met on **November 14th, 2018**. The program review checklist provided by the National Institutes of Health Office of Laboratory Animal Welfare (OLAW) and the 8th Edition of the Guide for the Care and Use of Laboratory Animals (2011) were used by the subcommittee to perform the program review. Summaries of animal welfare concerns, noncompliance issues, and trends from the semiannual inspection and PAM visits were included within the checklist to provide information for discussion.

Summaries of the deficiencies noted on the semiannual inspections are attached to this report.

A response detailing the resolution plan for any noted deficiencies is requested from each principal investigator (PI) for each deficiency (minor or significant) noted in areas for which they are responsible. A member of the IACUC or the Animal Welfare Analyst may conduct follow up visits to confirm that corrective actions addressing deficiencies noted during the inspection were completed.

In addition to the IACUC inspections, AAALAC International conducted a triennial site visit on November 12-13. Tentative results of the site visit are Continued Full Accreditation.

I. INSPECTION TEAMS

University City

Laboratories and Animal Facility (October 25th, 2018 9:00 a.m. to 12:00 p.m.) Rick Huneke, DVM Michael O'Connor, PhD

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Queen Lane

Laboratorics and Animal Facility (October 18th, 2018 9:00 a.m. to 12:00 p.m.) Rick Huneke, DVM Michael O'Connor, PhD

(b) (6)

New College Building

Laboratories and Animal Facility (October 22nd, 2018 9:00 a.m. to 12:00 p.m.) Rick Huneke, DVM

(b) (6)

II. INSTITUTIONAL POLICIES

All policies comply with the USDA and PHS policy and federal regulations. These policies are on the IACUC web site and are routinely reviewed and updated every three years as per requirements by the Office of Laboratory Animal Welfare (OLAW). Investigators are required to complete online CITI training for certification in the care and handling of laboratory animals. It is mandatory that all personnel handling animals complete this training. All investigators and personnel handling laboratory animals must participate in the animal welfare training and occupational health programs. The Office of Research insures that all investigators and laboratory personnel are certified in this program. Policies and procedure manuals for IACUC and other committees are also available at the Office of Research at 1505 Race St., Bellet Building, 10th Floor, Philadelphia, PA.

III. ANIMAL HOUSING

All animals are housed in appropriately sized cages or pens and in social groups *unless they must be housed alone for experimental reasons or because of social incompatibility*. Storage of food and bedding was proper in all animal facilities. Veterinary care included the use of anesthesia, analgesia, post-surgical care and euthanasia. Except previously described areas, surgical areas for both non-survival and survival surgery showed adequate organization and cleanliness in all of the sites, including satellite housing.

IV. EXCEPTIONS TO THE GUIDE OR USDA

- Continuous trio breeding is approved for (b) (6) s mice. As appropriate, weaning age of these mice is 21 days to decrease potential for overcrowded cage issues.
- In several protocols where rodents are debilitated or recovering from surgery or newly weaned, food may be provided on the floor of the cage to allow easier access.
- (b) (6), s protocol requests an extension in sanitization of the primary holding cage for rats during behavioral testing for up to one month. During the 3-4 week long testing period, the bedding pan under the cage will be changed weekly, and the inside of the chamber is cleaned such that any remaining bedding, food, or other refuse is removed and the chamber is wiped with 70% ethanol. Following the 3-4 week experiments the animals are removed, and the chambers are sent to cage wash where they are appropriately washed and disinfected by animal care staff.
- (b) (6) requested and the IACUC approved an exception to the USDA requirement for an elevated perch in the cat's cage following a spinal transection surgery under protocol 20489. Spinalized cats cannot reach an elevated perch, so the devices are not useful in this population. Additionally, such devices may result in injury to the animal should it become entrapped. Padded flooring is provided for the animal in the cage. Also, IACUC approved exception to not having litter boxes in cage following spinal cord surgery to prevent injury.
- (b) (6) requested permission with the suggestion of the attending veterinarian to house 1-3 day old piglets in the lab for up to 24 hours post surgery. These piglets were anesthetized for up to 4 hours. The lab contained a neonatal incubator to keep the piglets warm after anesthesia and to allow the lab staff to continually monitor and feed the piglets.
- (b) (6) performs aseptic toe clippings for identification purposes on pups aged 10-12 days without providing a justification for not using an alternative method.

V. PROGRAM REVIEW

Program Review Checklist – A subcommittee of the IACUC met on May 9th and used a program review checklist and the 8th Edition of the Guide for the Care and Use of Laboratory Animals (2011).

Deficiency Notes in the Animal Care and Use Program

- From the Guide for the Care and Use of Laboratory Animals (pg 16) "Animal Care Personnel caring for animals should be appropriately trained (see Appendix A, Education), and the institution should provide for formal and/or on-the-job training to facilitate effective implementation of the Program and the humane care and use of animals. Staff should receive training and/or have the experience to complete the tasks for which they are responsible"
 - Deficiency- There was a demonstrated lack of aseptic knowledge among research staff which was discovered during the AAALAC site visit. All personnel working with research animals are mandated to take initial training provided by the University Laboratory Animal Resources (ULAR) staff. The training is tailored to the activities specified on animal use protocol, including aseptic technique. The findings on the site visit suggest improvements to the current training program could improve the ability to facilitate effective implementation of humane care and use of animals.
 - Resolution- The Animal Welfare Analyst will observe surgery and provide training to those cited for improper aseptic technique during the AAALAC site visit. The Animal Welfare Analyst will also observe the initial ULAR training process and provide feedback on areas for improvement. The Director of ULAR will work with the training staff and make changes as necessary based on the feedback from the Animal Welfare Analyst. Training program?.
- From the Guide for the Care and Use of Laboratory Animals (pg 75) "As a method of identification of small rodents, toe-clipping should be used only when no other individual identification method is feasible. It may be the preferred method for neonatal mice up to 7 days of age as it appears to have few adverse effects on behavior and well-being at this age (Castelhano-Carlos et al. 2010; Schaefer et al. 2010), especially if toe clipping and genotyping can be combined. Under all circumstances aseptic practices should be followed. Use of anesthesia or analgesia should be commensurate with the age of the animals"
 - Deficiency- The IACUC approved (b) (6) s protocol # 20706 which includes toe clipping. The protocol does not include a written justification for the use of toe clipping over other available methods.
 - Resolution- The IACUC will develop a policy for genotyping (to include the appropriate use of toe clipping) and distribute the policy to researchers via the Drexel Website by June 2019.
- From the Guide for the Care and Use of Laboratory Animals (pg 21) "While engineering and administrative controls are the first considerations for the protection of personnel, PPE appropriate for the work environment, including clean institution-issued protective clothing, should be provided as often as necessary"
 - Deficiency- Some investigators are not wearing PPE as specified in their biosafety protocol when in the animal facility, citing that ULAR does not provide all PPE. Specifically, disposable PPE is provided by ULAR (gloves, gowns, hair bonnets, surgical masks, and booties), while non-disposable items such as goggles, lab safety glasses and face shield are not. However, the biosafety protocol states "It is the responsibility of the Principal Investigator to make arrangements for special protective outerwear (other than gloves, gowns, and shoe covers)"
 - The Office of Research, Regulatory Compliance unit will issue a reminder to all Principal Investigators to bring and wear protective eyewear in the animal facility either when hazardous agents are present, in any situation that includes a splash hazard or significant risk of eye injury, or as required by the biosafety protocol.
- From the Guide for the Care and Use of Laboratory Animals (pg 28) "When novel studies are proposed or information for an alternative endpoint is lacking, the use of pilot studies is an effective method for identifying and defining humane endpoints and reaching consensus among the PI, IACUC, and veterinarian. A system for communication with the IACUC should be in place both during and after such studies."
 - o Deficiency- The system to track when a researcher is required to report to the IACUC on a pilot

study is inefficient. This has been accomplished by restricting the number of animals a researcher is able to order. Once the pilot study has been reported and approved, the number of animals able to be ordered will be extended to the full amount. The current database system does not distinguish between the number of animals which are able to be ordered for pilot studies and the total amount approved on the protocol.

Resolution- The current work-around will remain in place until a new electronic IACUC protocol management system is put into operation. However, the current system for tracking and ordering animals is using an outdated version of Microsoft and cannot be serviced by the IT department. Additionally, it only works on old desktops and cannot be added to new computers as they are replaced. ULAR currently only has one remaining computer which can access this database. Also, the database often fails or collects information making tracking of animals, animal ordering and per diem charge backs unreliable.

VI. CONCLUSION

Deficiencies were communicated to the respective Principal Investigators with plans for action to remedy the problem. The principal investigators were instructed to report to the committee within 14 working days with the actions they have taken to prevent these deficiencies from recurring. There were no minority opinions.

This report was adopted by the Drexel University IACUC at its meeting on December 12, 2018.

Respectfully submitted,

Michael O'Connor, Ph.D.

Chair, Institutional Animal Care and Use Committee

Inspection Report, November 2018

____ I accept the report as presented

____ I am making the following recommendations

(b) (6)

Aleister Saunders, Ph.D.

Institutional Official

1.14.19

Date

THIS IS TO CERTIFY THAT WE THE UNDERSIGNED HAVE REVIEWED AND APPROVED THE ATTACHED DREXEL UNIVERSITY ANIMAL CARE AND USE COMMITTEE SEMI-ANNUAL REPORT TO THE INSTITUTIONAL OFFICAL ON December 12th, 2018.

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	Michael O'Connor, PhD	Richard Huneke, DVM, MPH		(b) (6)
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Fall 2018 SIGNIFICANT Deficiency Breakdown Summary

Significant Deficiency Noted	Number noted
Anesthetic Expiration Label	2
Expired Anesthesia or Analgesia	6
TOTAL SIGNIFICANT DEFICIENCIES NOTED	8

Responsible Party	Deficiency Type	Deficiency Notes	Severity	Resolution Plan	Resolution Schedule
(b) (6)	Expiration Label (Anesthetic)	Vials of diluted ketamine were not labeled with expiration dates. Unlabeled agents used in animals could be expired. According to the Guide for the Care and Use of Laboratory Animals, "Agents that provide anesthesia and analgesia must be used before their expiration dates and should be acquired, stored, their use reported, and disposed of legally and safely."	Significant	Please label all vials with expiration dates	24 hours
-	Expiration Label (Anesthetic)	Ketamine/Xylazine cocktail was not labeled with a preparation date. Also the stock bottles of ketamine and xylazine were not available to check for expiration dates. According to Drexel's Policy for : Pharmaceutical Mixtures MUST be clearly labeled with compound names, concentrations, and date of preparation (expiration date shall be 30 days after date of preparation).	Significant	Please label all cocktails with the preparation date and dispose of the cocktail within 30 days of preparation.	24 hours
-	Expired Anesthetic	One bottle of Euthasol expired 7/2018. According to the Guide for the Care and Use of Laboratory Animals, "Agents that provide anesthesia and analgesia must be used before their expiration dates and should be acquired, stored, their use reported, and disposed of legally and safely."	Significant	The drug was labeled "expired" and placed in a separate locked area at the time of inspection	Complete d at time of inspection

Fall 2018 SIGNIFICANT Deficiency Breakdown Summary

Responsible Party	Deficiency Type	Deficiency Notes	Severity	Resolution Plan	Resolution Schedule
(b) (6)	Expired Anesthetic	One bottle of Buprenorphine SR expired 8/25/18. Three bottles of Euthasol had expired 8/18. According to the Guide for the Care and Use of Laboratory Animals, "Agents that provide anesthesia and analgesia must be used before their expiration dates and should be acquired, stored, their use reported, and disposed of legally and safely."	Significant	The drugs were labeled "expired" and placed in a separate locked area at the time of inspection.	Complete d at time of inspection
	Expired Anesthetic	One bottle of isoflurane was discovered without an expiration date. The most recent shipping label for isoflurane had an expiration date of 02/2017.	Significant	Please ensure the expiration date of each product is clearly labeled. Please also properly dispose of the expired agent.	24 hours
	Expired Anesthetics	One green centrifuge tube of Ketamine/Xylazine expired and was not labeled. All expired controlled substances must be properly labeled according to the DEA.	Significant	Create a separate container labeled for expired drug vials to be placed into in controlled substance area.	24 hours
	Expired Anesthetics	One bottle of Euthasol expired in 2015. According to the Guide for the Care and Use of Laboratory Animals, "Agents that provide anesthesia and analgesia must be used before their expiration dates and should be acquired, stored, their use reported, and disposed of legally and safely."	Significant	Please store in an area separate from actively used substances and dispose the expired substance in accordance with DEA regulations.	24 hours

Fall 2018 SIGNIFICANT Deficiency Breakdown Summary

Responsible Party	Deficiency Type	Deficiency Notes	Severity	Resolution Plan	Resolution Schedule
(b) (6)	Expired Anesthetic	In plastic set of drawers, there was one bottle of expired Isoflurane. According to the Guide for the Care and Use of Laboratory Animals, "Agents that provide anesthesia and analgesia must be used before their expiration dates and should be acquired, stored, their use reported, and disposed of legally and safely."	Significant	Please dispose of expired materials.	24 hours

Minor Deficiency Noted	Number noted
Agent Label	4
Agent Storage	2
Cage Card	7
Controlled Drug Storage	1
Dead Animal Found	1
Drug Label	1
Expired Agent	6
Expired Product	19
Food Storage	1
Environment	2
Lab Equipment	1
Lab Protocol	1
Product Label	3
Protocol Deviation	3
Record Storage	2
Recordkeeping	3
Sanitation	31
Waste Scavenger	1
TOTAL MINOR DEFICIENCIES NOTED	89

Responsible Party	Deficiency Type	Deficiency Notes	Severity	Resolution Plan	Resolution Schedule
(b) (6)	Agent Label	One secondary container of alcohol was not labeled with a date of expiration. Agents should be labeled and used within their date of expiration to ensure appropriate effectiveness.	Minor	Please label all containers with an expiration date	24 hours
	Agent Label	One umarked 50ml conical tube was located in the cabinet. One bottle of Nolvasan did not have an expiration date. Agents should be labeled and used within their date of expiration to ensure appropriate effectiveness.	Minor	Please label or discard the unmarked conical tube and please label the bottle of Nolvasan with the appropriate expiration date	24 hours
	Agent Label	No year of expiration was found on one bottle of Accell. Unlabeled agents could be expired. Any drugs, or medications or substances used with live animals must be used prior to their expiration date.	Minor	Please label all agents appropriately	24 hours

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Responsible Party	Deficiency Type	Deficiency Notes	Severity	Resolution Plan	Resolution Schedule
(b) (6)	Agent Label	No expiration date on container of "Yogurt Chips" or water bottles used for animals in recovery. Unlabeled agents used in animals could be expired. Food and water given to animals used in research must be used before the expiration date.	Minor	Please label food and water with expirations dates and dispose of expired items.	1 week
	Agent Storage	Bottles of a corrosive agents being stored on metal rack is causing rust to form.	Minor	Please store all corrosive agents in a secondary container	24 hours
	Agent Storage	Saline was stored with a needle sticking into the top of the bottle. This can cause contamination of the substance.	Minor	Please store all substances with an appropriate lid.	24 hours
	Cage Card	One cage card was labeled with just the name of a laboratory member and did not. have the name of the PI or protocol number.	Minor	Please label all cage cards with the protocol number and name of the Pl	24 hours

Responsible Party	Deficiency Type	Deficiency Notes	Severity	Resolution Plan	Resolution Schedule
(b) (6)	Cage Card	One cage was labeled with a single housed cage card which did not have the reason for single housing listed. According to Drexel's program description to AAALAC "Singly housed animals are identified by a color coded cage card denoting single housing and justification for doing so."	Minor	Please complete the cage card with a reason for single housing.	24 hours
	Cage Card	1 cage card on rack to the left of the door upon entry, incorrectly formatted. According to the Guide for the Care and Use of Laboratory Animals, "Identification cards should include the source of the animal, the strain or stock, names and contact information for the responsible investigator(s), pertinent dates (e.g., arrival date, birth date, etc.), and protocol number when applicable."	Minor	Please fill out cage card appropriately.	24 hours
	Cage Card	Animals cages contained "Single-housed" cage cards, but did not include a reason for the single housing. According to Drexel's program description to AAALAC "Singly housed animals are identified by a color coded cage card denoting single housing and justification for doing so."	Minor	Please complete the reason for single housing on the cards	24 hours
	Cage Card	Cage Cards were labeled with delivery dates which included the day and month but did not include the year.	Minor	Please include the year when labeling cages with the delivery dates.	24 hours

Responsible Party	Deficiency Type	Deficiency Notes	Severity	Resolution Plan	Resolution Schedule
(b) (6)	Cage Card	Animals cages contained "Single-housed" cage cards, but did not include a reason for the single housing. According to Drexel's program description to AAALAC "Singly housed animals are identified by a color coded cage card denoting single housing and justification for doing so."	Minor	Please complete the reason for single housing on the cards	24 hours
	Cage Cards	Animals cages contained "Single-housed" cage cards, but did not include a reason for the single housing. According to Drexel's program description to AAALAC "Singly housed animals are identified by a color coded cage card denoting single housing and justification for doing so."	Minor	Please complete the reason for single housing on the cards	24 hours
	Controlled Drug Storage	Controlled Drugs were in a box sitting in the open on a lab bench and not stored in a secured, locked box.	Minor	Please arrange for controlled substance to be stored in accordance with DEA regulations	1 week
	Dead animal found	In the annex entry area of room suite, there was a dirty cage on the designated dirty cage rack that contained one dead pup. According to the IACUC policy on proper euthanasia and handling of dead animals, "The carcass should be disposed of in a bag and placed in a designated freezer ."	Minor	Please dispose of dead animals appropriately at all times.	24 hours

Responsible Party	Deficiency Type	Deficiency Notes	Severity	Resolution Plan	Resolution Schedule
(b) (ć	ⁱ⁾ Drug Label	A container of pre-loaded syringes of Buprenorphine SR was not labeled. All syringes and vials containing controlled substances or other agents to be used in animals must be properly labeled.	Minor	The container holding the syringes was appropriately labeled at the time of inspection	Completed at time of inspection
	Expired Agent	One bottle of saline was found to be expired in 2015. Any drugs, or medications used with live animals must be used prior to their expiration date.	Minor	Please dispose of the expired saline	24 hours
	Expired Agent	A bottle of expired saline was discovered. Any drugs, or medications or substances used with live animals must be used prior to their expiration date.	Minor	Please dispose of the expired saline	24 hours
	Expired Agent	One bottle of Saline expired in 2011. Two bottles of Heparin expired in 2016. Any drugs, or medications or substances used with live animals must be used prior to their expiration date.	Minor	Please dispose of the expired saline and Heparin	24 hours

Responsible Party	Deficiency Type	Deficiency Notes	Severity	Resolution Plan	Resolution Schedule
Huneke	Expired Agent	One bottle of expired alcohol was discovered. IACUC Autoclaving policy states the following about chemical sterilization "Freshly prepared solutions must be used, and the expiration date of the prepared chemical must be labeled on the container."	Minor	Please remove expired products and refrain from using expired products for sterilization purposes.	24 hours
Huneke	Expired Agent	Expired Accel container from 1/2018. Expired bleach and unreadable "Enzol" cleaner expiration date.	Minor	Bleached and Accel poured out, Enzol will be discarded.	24 hours
Huneke	Expired Agent	Accel expires 11/18 (around time of AAALAC inspection). Isoflurane machine has TWO labels on it with dates. One is appropriate and has an expiration date in 2019. The other says the machine has expired in 2013.	Minor	Please remove or deface the incorrect label of expiration.	24 hours
(b) (6)	Expired Product	One box of blood collection needles had expired. According to Drexel's Policy for Surgery and Postsurgical Care of Rodents for Major and Minor survival surgery "The use of sterile instruments, suture material and supplies is required."	Minor	The box was labeled as acute use only at the time of inspection.	Completed at inspection

Responsible Party	Deficiency Type	Deficiency Notes	Severity	Resolution Plan	Resolution Schedule
(b) (б)	Expired Product	One expired syringe was discovered. According to Drexel's Policy for Surgery and Postsurgical Care of Rodents for major and Minor survival surgery "The use of sterile instruments, suture material and supplies is required."	Minor	The expired syringe was discarded at the time of inspection	Completed at time of inspection
	Expired Product	One box of expired swab sticks was discovered. According to Drexel's Policy for Surgery and Postsurgical Care of Rodents for major and Minor survival surgery "The use of sterile instruments, suture material and supplies is required."	Minor	The expired swabs were discarded at the time of inspection	Completed at time of inspection
	Expired Product	A disposable scalpel expired in 2012. According to Drexel's Policy for Surgery and Postsurgical Care of Rodents for major and Minor survival surgery "The use of sterile instruments, suture material and supplies is required."	Minor	Please dispose of the expired scalpel.	24 hours
	Expired Product	Expired scalpel blades were found in the lab. According to Drexel's Policy for Surgery and Postsurgical Care of Rodents for major and Minor survival surgery "The use of sterile instruments, suture material and supplies is required."	Minor	Please dispose the expired scalpel blades	Resolved at the time of inspection

Responsible Party	Deficiency Type	Deficiency Notes	Severity	Resolution Plan	Resolution Schedule
(b) (6)	Expired Product	Expired surgical gloves were discovered in the lab. According to Drexel's Policy for Surgery and Postsurgical Care of Rodents for major and Minor survival surgery "The use of sterile instruments, suture material and supplies is required."	Minor	Please dispose the Expired Product or label them "for acute terminal use only"	1 week
Huneke, ^{(b) (6)}	Expired Product	Expired suture was found in the area. According to Drexel's Policy for Surgery and Postsurgical Care of Rodents for major and Minor survival surgery "The use of sterile instruments, suture material and supplies is required."	Minor	Please dispose of the suture material or label "For terminal use only"	24 hours
Huneke/ ^{(b) (6)}	Expired Product	Expired blood tubes were discovered.	Minor	Please dispose of the expired tubes	24 hours
(b) (6)	Expired Product	One ethanol bottle expired 10/2015. Any drugs, or medications used with live animals must be used prior to their expiration date.	Minor	Please dispose of the expired liquid	24 hours

Responsible Party	Deficiency Type	Deficiency Notes	Severity	Resolution Plan	Resolution Schedule
(b) (6)	Expired Product	Expired surgical gloves found in labeled plastic container in the back of the room. According to Drexel's Policy for Surgery and Postsurgical Care of Rodents for major and minor survival surgery, " Aseptic technique including clipping and disinfection of the surgical site and use of sterile gloves and instruments is required for minor procedures.	Minor	Please discard expired sterile gloves	24 hours
	Expired Product	One box of expired bone wax was discovered. Flourogold in refrigerator outside of prep room was not labeled with opening or expiration date. Any drugs, or medications or substances used with live animals must be used prior to their expiration date.	Minor	Discarded at time of inspection	N/A
Huneke	Expired Product	Expired Hydrochloric acid from 1/2018. IACUC's autoclaving and chemical sterilization policy is as follows, "Freshly prepared solutions must be used, and the expiration date of the prepared chemical must be labeled on the container."	Minor	Dispose of expired cleaning agents	24 hours
Huneke	Expired Product	No expiration or shelf life date of piglet nutritional supplements "Mega Pig 08" and "First Pulse D" was noted. According to the Guide for the Care and Use of Laboratory Animals " The user should know the date of manufacture and other factors that affect the food's shelf life"	Minor	Please contact the manufacturer to find the shelf life of the product.	1 week

Responsible Party	Deficiency Type	Deficiency Notes	Severity	Resolution Plan	Resolution Schedule
Huneke	Expired Product	Several small plastic containers of buffered formalin expired in 2016. The bottle also was not labeled with expiration date or expired. IACUC policy states: "Freshly prepared solutions must be used, and the expiration date of the prepared chemical must be labeled on the container."	Minor	ULAR staff have already planned to contact EH&S to dispose of the expired formalin properly and label with expiration date in the future.	24 hours
Huneke	Expired Product	In plastic set of drawers, in one unlabeled drawer was an expired bottle of PBS.	Minor	Please dispose of Expired Products.	24 hours
Huneke	Expired Product	The date of expiration on bottle of Rescue illegible. Agents should be clearly labeled and used within their date of expiration to ensure appropriate effectiveness.	Minor	ULAR plans to correct with properly labeled date of expirations	24 hours
Huneke	Expired Product	Found: expired endotracheal tube sterilization dated, 2014 expired sterilized gauze and chuck pack. Expired cautery pens, expired surgical instrument packs, some surgical packs not labeled with expiration dates, Buprenorphine expired 6/2017, expired popcorn kernels 7/2018, 2008 expired suture. All items used in lab animal research must be used before their expiration date.	Minor	All expired products were properly disposed of, or labeled "for acute use only," relabeled for training, or set for re- sterilization at the time of inspection.	Completed at time of inspection

Responsible Deficiency **Deficiency Notes Resolution Plan** Severity Resolution Party Schedule Type (b) (6) Expired 2 expired bottles of sterile water and 2010 Discard of expired items. Minor 24 hours Product expired TAO triple antibiotic ointment. 1 Provide ULAR with access tube of expired non-spermicidal to lock box for inspection. lubricating jelly and fluids. Expired vapor rub, alcohol, drapes, and 2016 expired pig arteries in fixative There is also a lock box that ULAR and AAALAC inspectors needs access to for inspection. One container of food did not contain an Please include an **Food Storage** 24 hours Minor expiration date. According to the Guide for expiration date on the the Care and Use of Laboratory Animal's label "The user should know the date of manufacture and other factors that affect the food's shelf life." On October 25th the room humidity was Humidity Minor Please note the low 2 weeks recorded at 29%. The acceptable range as humidity and if necessary indicated on the door sheet is 30-70%. take actions to ensure the humidity is maintained in the appropriate range Please defrost the freezer. The black refrigerator near the front door 1 month Lab Equipment Minor next to the CO2 tanks should be defrosted. It is a good laboratory practice to keep ice growth to a minimum in freezers and refrigerators used in laboratory animal research

Responsible Party	Deficiency Type	Deficiency Notes	Severity	Resolution Plan	Resolution Schedule
(b) (6)	Lab Protocol	There was a drinking cup with tea in the surgery area by the computer. According to the Guide for the Care and Use of Laboratory Animals, Personnel should not be permitted to eat, drink, use tobacco products, apply cosmetics, or handle or apply contact lenses in rooms and laboratories where animals are housed or used.	Minor	Please do not eat or drink in the surgery areas.	24 hours
	Maintenance	Unpainted wall near entrance of animal holding area. The area and equipment used for housing and care of research animals according to the IACUC's sanitization policy must have "a sanitizable surface and not be made of porous material; wooden surfaces are not acceptable, unless painted with a smooth, non -porous material." The emergency shower had not been certified/inspected since 7/2015.	Minor	Contact facilities to paintContact facilities to have emergency shower inspected.	1 month
	Product label	No dates were found on the sterile surgical packs. The Drexel IACUC's Autoclaving policy is as follows: "Packs of sterile instruments or materials stored for more than a week should be double - wrapped in packaging which is impermeable to water. The date of sterilization should be clearly marked on the outer wrapper. Expiration dates vary with packaging materials, but a general guideline is two months from the date of sterilization. Using commercially available plastic dust covers or storing in closed cabinetry will extend the shelf life to 6 - 12 months."	Minor	Please include a date that the surgical instruments are sterilized.	24 hours

Responsible Party	Deficiency Type	Deficiency Notes	Severity	Resolution Plan	Resolution Schedule
(b) (é	⁵⁾ Product label	Unlabeled syringes to be reused taped onto wall.	Minor	Please remove syringes from back wall.	2 weeks
Huneke	Product label	The mouse food bin used by ULAR staff was labeled with date of opening in 2019. Any drugs, or medications, food or substances used with live animals must be used prior to their expiration date.	Minor	ULAR plans to correct date of opening.	24 hours
(b) (6	⁵⁾ Protocol Deviation	In the Animal Care log for cages of animals inside of the incubator, indicated a time that had not yet happened as the time checked on. The room was visited at 11:18 am and the time written in the log that the animals were checked on was 1:49.	Minor	Please be sure to always indicate correct times in the animal care log for all animals.	24 hours

Responsible Party	Deficiency Type	Deficiency Notes	Severity	Resolution Plan	Resolution Schedule
(b) (6	Protocol deviation	Multiple cages had animals with animal ages greater than 1 year. The protocol states the animals will be used by12 months of age age.	Minor	Please euthanize animals according to the timeline in the protocol or submit an amendment to change the timeline.	1 week
	Protocol deviation	Breeding cage setups were dated with 1/2017 and 4/2017.	Minor	Please retire animals according to the timeline in the protocol or submit an amendment to change the timeline.	1 week
	Record Storage	Cd recordings VHS's and other recording records of animal activity was kept in an area cabinet which was not locked. According to Drexel's Recording Policy recordings of research animals should "Keep storage devices (tapes, CD, DVD, memory sticks, flash cards etc) in a secure, locked area with very limited access."	Minor	Please store the CDs in an appropriately locked area.Some were removed at the time of inspection	1 week
	Record Storage	Research videotapes were found unsecured on a table. According to Drexel's Recording Policy recordings of research animals should "Keep storage devices (tapes, CD, DVD, memory sticks, flash cards etc) in a secure, locked area with very limited access."	Minor	Please store all research video in a secure area	1 week

Responsible Party	Deficiency Type	Deficiency Notes	Severity	Resolution Plan	Resolution Schedule
(b) (6	Recordkeeping	There was no record of sterility via autoclave strips. According to Drexel's Policy for Autoclaving " A log must be maintained showing the dates the instruments were autoclaved. The actual internal pack sterilization monitor, showing adequate sterilization, must be attached to this log. These logs should be available for inspection by the IACUC, regulatory agencies and AAALAC."	Minor	Please include the autoclave strips in the records	24 hours
	Recordkeeping	Some pages of surgical records did not indicate surgeon name. According to the IACUC Policy for Surgery and Postsurgical Care of Rodents, "All surgical records should include the following information: the surgeon, the anesthetic agent(s) and dose."	Minor	Please correct and ensure all requirement of recordkeeping are being fulfilled.	24 hours
	Recordkeeping	The appropriate dose of Meloxicam was administered directly after surgery and post-operatively but was not recorded. According to Drexel's Policy for Surgery and Postsurgical Care of Rodents "Post- surgical records must also be maintained for each animal, indicating the time when the animal awakens from anesthetic, animal observations including any adverse signs during the post-operative period, agent, dose and time of analgesic administration, and the name of the individual performing the post-operative care."	Minor	Please record all doses of Meloxicam administered	24 hours

Responsible Party	Deficiency Type	Deficiency Notes	Severity	Resolution Plan	Resolution Schedule
(b) (6)	Sanitation	Vacuums present do not have HEPA filters. Because vacuums can aerosolize allergens, they should not be used unless the exhaust is HEPA filtered.	Minor	All vacuums without HEPA filters must be removed from the laboratory	2 weeks
	Sanitation	The floor was dirty. According to the Guide for the Care and Use of Laboratory Animals, "All components of the animal facility, including animal rooms and support spaces (e.g., storage areas, cage- washing facilities, corridors, and procedure rooms) should be regularly cleaned and disinfected as appropriate to the circumstances and at a frequency based on the use of the area and the nature of likely contamination."	Minor	Please arrange with housekeeping for the floor to be thoroughly cleaned.	2 weeks
Huneke	Sanitation	The room was not in use however, it must be cleaned. According to the Guide for the Care and Use of Laboratory Animals, "all components of the animal facility, including animal rooms and support spaces should be regularly cleaned and disinfected as appropriate to the circumstances and at a frequency determined by the use of the area and the nature of likely contamination."	Minor	ULAR staff plans to clean	2 weeks

Responsible	Deficiency	Deficiency Notes	Severity	Resolution Plan	Resolution
Party	Туре				Schedule
Huneke	Sanitation	Rabbit runs are not currently in use however there were dead bugs found in many of the runs as well as hay debris on floor and kitchen area counter. There was a broom and squeegee on stored on the floor. Sweeping equipment should be hung on a rack and kept off the floor. There was exposed rust on the doorway wall corners. According to the Guide for the Care and Use of Laboratory Animals, "all components of the animal facility, including animal rooms and support spaces should be regularly cleaned and disinfected as appropriate to the circumstances and at a frequency determined by the use of the area and the nature of likely contamination."	Minor	ULAR staff has plans to clean and contact facilities to finish installing the corner guards of rusty doorway walls.	2 weeks
Huneke	Sanitation	The first animal run was soiled. No animals were housed at the time of inspection. According to the Guide for the Care and Use of Laboratory Animals, "all components of the animal facility, including animal rooms and support spaces should be regularly cleaned and disinfected as appropriate to the circumstances and at a frequency determined by the use of the area and the nature of likely contamination."	Minor	ULAR staff has plans to clean.	2 weeks

Responsible Party	Deficiency Type	Deficiency Notes	Severity	Resolution Plan	Resolution Schedule
(b) (6	Sanitation	Fur from animals found in behavioral place preference boxes. In the IACUC's sanitation policy it is stated, "Individuals using private or shared animal research equipment are responsible for maintaining proper sanitization before, during, and directly after each use."	Minor	Sanitize boxes so that they are appropriate for animal testing.	24 hours
	Sanitation	The room was cluttered. There was a blue tarpol lying on the floor underneath the table – hinder cleaning the area. According to the Guide for the Care and Use of Laboratory Animals, "All components of the animal facility, including animal rooms and support spaces (e.g., storage areas, cage-washing facilities, corridors, and procedure rooms) should be regularly cleaned and disinfected as appropriate to the circumstances and at a frequency based on the use of the area and the nature of likely contamination."	Minor	Please organize the room	1 week
	Sanitation	The room was last noted to be cleaned on 1/12/18. According to the Guide for the Care and Use of Laboratory Animals, "all components of the animal facility, including animal rooms and support spaces should be regularly cleaned and disinfected as appropriate to the circumstances and at a frequency determined by the use of the area and the nature of likely contamination.".	Minor	Please record the room cleaning each time it is performed.	1 week

Responsible Party	Deficiency Type	Deficiency Notes	Severity	Resolution Plan	Resolution Schedule
(b) (6)	Sanitation	The overhead camera was stabilized with old, detached duct tape.	Minor	Please replace with fresh tape.	1 week
	Sanitation	The surgery equipment had clipped fur present. Equipment coming into contact with animals is not being periodically ATPase tested by ULAR to ensure proper sanitation. According to the Guide for the Care and Use of Laboratory Animals, "All components of the animal facility, including animal rooms and support spaces (e.g., storage areas, cage-washing facilities, corridors, and procedure rooms) should be regularly cleaned and disinfected as appropriate to the circumstances and at a frequency based on the use of the area and the nature of likely contamination."	Minor	Please clean the surgical areas. Please also plan a swab time to be done with ULAR after a sanitation of materials coming into contact with animals.	1 week
	Sanitation	The plus sign stress test apparatus had bedding present from most recent use. Equipment coming into contact with animals should be periodically ATPase tested by ULAR to ensure proper sanitation According to the Guide for the Care and Use of Laboratory Animals, "All components of the animal facility, including animal rooms and support spaces (e.g., storage areas, cage-washing facilities, corridors, and procedure rooms) should be regularly cleaned and disinfected as appropriate to the	Minor	Please clean the testing apparatuses. Please also plan a swab time to be done with ULAR after a sanitation of materials coming into contact with animals.	1 week

Responsible Party	Deficiency Type	Deficiency Notes	Severity	Resolution Plan	Resolution Schedule
		circumstances and at a frequency based on the use of the area and the nature of likely contamination." The Drexel IACUC's sanitation policy is as follows: "ULAR can monitor the effectiveness of the procedure by swabbing representative equipment after the sanitization process. Monitoring the effectiveness of sanitization should be done annually to comply with the Guide for the Care and Use of Laboratory Animals."			
Hueneke, (b) (6)	Sanitation	Brooms were sitting directly on the flood. Sweeping equipment should be hung on a rack and kept off the floor.	Minor	Please hang brooms on the appropriate rack	1 week
Huneke, (b) (6)	Sanitation	Soiled bedding was discovered in the sink. The room was found to be generally messy and unkept. According to the Guide for the Care and Use of Laboratory Animals, "All components of the animal facility, including animal rooms and support spaces (e.g., storage areas, cage-washing facilities, corridors, and procedure rooms) should be regularly cleaned and disinfected as appropriate to the circumstances and at a frequency based on the use of the area and the nature of likely contamination."	Minor	Please remove the soiled bedding and clean the area.	24 hours

Responsible Party	Deficiency Type	Deficiency Notes	Severity	Resolution Plan	Resolution Schedule
(b) (6)	Sanitation	There was no visible cleaning solution for the behavior chamber or other areas. Water bottles for white box behavior tests for rodents unable to be autoclaved. Cleaned with "soap and water." Equipment coming into contact with animals should be periodically ATPase tested by ULAR to ensure proper sanitation. According to the Guide for the Care and Use of Laboratory Animals, "All components of the animal facility, including animal rooms and support spaces (e.g., storage areas, cage-washing facilities, corridors, and procedure rooms) should be regularly cleaned and disinfected as appropriate to the circumstances and at a frequency based on the use of the area and the nature of likely contamination." The Drexel IACUC's sanitation policy is as follows: "ULAR can monitor the effectiveness of the procedure by swabbing representative equipment after the sanitization process. Monitoring the effectiveness of sanitization should be done annually to comply with the Guide for the Care and Use of Laboratory Animals. "	Minor	Please make cleaning agents available. Please clean the testing apparatuses. Please also plan a swab time to be done with ULAR after a sanitation of materials coming into contact with animals.	1 week

Responsible Party	Deficiency Type	Deficiency Notes	Severity	Resolution Plan	Resolution Schedule
Huneke, ^{(b) (6)}	Sanitation	Dead bugs were found in empty cages (storage). According to the Guide for the Care and Use of Laboratory Animals, "all components of the animal facility, including animal rooms and support spaces should be regularly cleaned and disinfected as appropriate to the circumstances and at a frequency determined by the use of the area and the	Minor	Please sanitize the cages.	1 week
	Sanitation	nature of likely contamination.".The surgical area was unclean and contained granular dirt and fecal matter.According to the Guide for the Care and Use of Laboratory Animals, "all components of the animal facility, including animal rooms and support spaces should be regularly cleaned and disinfected as appropriate to the circumstances and at a frequency determined by the use of the area and the nature of likely contamination.".	Minor	Please clean this area	1 week
	Sanitation	The paper base to the behavioral arena was in older condition and stained. According to the Guide for the Care and Use of Laboratory Animals, "all components of the animal facility, including animal rooms and support spaces should be regularly cleaned and disinfected as appropriate to the circumstances and at a frequency determined by the use of the area and the nature of likely contamination.".	Minor	Please replace the paper	24 hours

Responsible Party	Deficiency Type	Deficiency Notes	Severity	Resolution Plan	Resolution Schedule
(b) (6)	Sanitation	The room had a tripod laying on the floor which interfered with room sanitation According to the Guide for the Care and Use of Laboratory Animals, "All components of the animal facility, including animal rooms and support spaces (e.g., storage areas, cage-washing facilities, corridors, and procedure rooms) should be regularly cleaned and disinfected as appropriate to the circumstances and at a frequency based on the use of the area and the nature of likely contamination."	Minor	Please tidy the room	1 month
	Sanitation	The clippers used to shave the animal's fur needed to be cleaned.	Minor	Please clean the clippers	24 hours
	Sanitation	Mini vacuum in drawer with clippers needs a HEPA filter. Because vacuums can aerosolize allergens, they should not be used unless the exhaust is HEPA filtered.	Minor	All vacuums without HEPA filters must be removed from the laboratory	1 week

Responsible Party	Deficiency Type	Deficiency Notes	Severity	Resolution Plan	Resolution Schedule
(b) (б)	Sanitation	The room was generally messy and unkempt. According to the Guide for the Care and Use of Laboratory Animals, "All components of the animal facility, including animal rooms and support spaces (e.g., storage areas, cage-washing facilities, corridors, and procedure rooms) should be regularly cleaned and disinfected as appropriate to the circumstances and at a frequency based on the use of the area and the nature of likely contamination."	s generally messy and cording to the Guide for the of Laboratory Animals, "All of the animal facility, mal rooms and support torage areas, cage-washing idors, and procedure rooms) ularly cleaned and s appropriate to the s and at a frequency based the area and the nature of ination." ing found on red heating pad of surgery area. According for the Care and Use of himals, "All components of cility, including animal rooms paces (e.g., storage areas, facilities, corridors, and oms) should be regularly lisinfected as appropriate to nces and at a frequency use of the area and the ly contamination." Minor Please clean heating pad for animals Minor Please clean beating pad for animals Please clean beating pad for animals Please clean beating pad for animals Please clean up lab	1 month	
	Sanitation	Fur and bedding found on red heating pad near the door of surgery area. According to the Guide for the Care and Use of Laboratory Animals, "All components of the animal facility, including animal rooms and support spaces (e.g., storage areas, cage-washing facilities, corridors, and procedure rooms) should be regularly cleaned and disinfected as appropriate to the circumstances and at a frequency based on the use of the area and the nature of likely contamination."	Minor		1 week
	Sanitation	The lab was generally messy and unkept. Dusty and loose but packaged needles not in proper boxes. According to the Guide for the Care and Use of Laboratory Animals, "All components of the animal facility, including animal rooms and support spaces (e.g., storage areas, cage- washing facilities, corridors, and procedure rooms) should be regularly cleaned and disinfected as appropriate to the	Minor	Please clean up lab	1 month

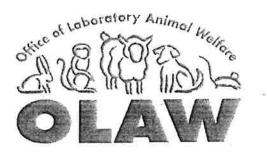
Responsible Party	Deficiency Type	Deficiency Notes	Severity	Resolution Plan	Resolution Schedule
		circumstances and at a frequency based on the use of the area and the nature of likely contamination."			
(b) (6)	Sanitation	Several cardboard boxes were found in this animal procedure area. Cardboard is not sanitizable and hinders the ability to appropriately clean the area. According to the Guide for the Care and Use of Laboratory Animals, "All components of the animal facility, including animal rooms and support spaces (e.g., storage areas, cage-washing facilities, corridors, and procedure rooms) should be regularly	Minor	Carboard boxes need to be removed from animal procedure area. Contents may be placed in a sanitizable storage container.	1 month
	Sanitation	cleaned and disinfected as appropriate to the circumstances and at a frequency based on the use of the area and the nature of likely contamination." Cloth surgery drapes (blue drapes) were found in third drawer of prep area, soiled with bedding and feces. All materials used for animal surgeries should be properly washed and or sanitized.	Minor	Wash or dispose of surgery chucks	24 hours

Responsible Party	Deficiency Type	Deficiency Notes	Severity	Resolution Plan	Resolution Schedule
(b) (6)	Sanitation	Cardboard boxes were located in the laboratory areas. Cardboard is not able to be sanitized. According to the Guide for the Care and Use of Laboratory Animals, "All components of the animal facility, including animal rooms and support spaces (e.g., storage areas, cage-washing facilities, corridors, and procedure rooms) should be regularly cleaned and disinfected as appropriate to the circumstances and at a frequency based on the use of the area and the nature of likely contamination."	Minor	Please remove the cardboard.	1 week
	Sanitation	The anesthetic chamber was soiled. According to the Guide for the Care and Use of Laboratory Animals, "All components of the animal facility, including animal rooms and support spaces (e.g., storage areas, cage-washing facilities, corridors, and procedure rooms) should be regularly cleaned and disinfected as appropriate to the circumstances and at a frequency based on the use of the area and the nature of likely contamination."	Minor	Please clean the chamber	24 hours
	Sanitation	Dirty water bottles were stored next to fresh water bottles. According to the Guide for the Care and Use of Laboratory Animals "Watering devices, such as drinking tubes and automated water delivery systems, should be checked frequently to ensure appropriate maintenance, cleanliness, and operation."	Minor	All bottles were removed at time of inspection	Completed

Responsible Party	Deficiency Type	Deficiency Notes	Severity	Resolution Plan	Resolution Schedule
(b) (6)	Sanitation	One broom was found stored on the floor. Sweeping equipment should be hung on a rack and kept off the floor.	Minor	Please store all sweeping supplies on a rack off of the floor	24 hours
	Sanitation	A broom was stored on the floor. Sweeping equipment should be hung on a rack and kept off the floor.	Minor	Please store all sweeping supplies on a rack off of the floor	1 week.
	Sanitation	The rooms were dirty. According to the Guide for the Care and Use of Laboratory Animals, "all components of the animal facility, including animal rooms and support spaces should be regularly cleaned and disinfected as appropriate to the circumstances and at a frequency determined by the use of the area and the nature of likely contamination.".	Minor	Please tidy the room. Please also thoroughly clean the floor and benchtop	2 weeks
	Expired Product	Isoflurane machines out of date but they will be visited and certified by the end of the month. Anesthesia machines used for animal research need to be maintained for proper function according to the manufacturer standards.	Minor	Date for inspection has been set before the end of the month. No surgery should be conducted until the machine is inspected.	2 weeks

Responsible Party	Deficiency Type	Deficiency Notes	Severity	Resolution Plan	Resolution Schedule
(b) (б)	Waste Scavenger	The waste gas canister was started on 4/18 and one weight had been recorded since that time. The canister should be weighed and the weight should be recorded with each use. The charcoal canister for waste gas scavenging was not weighted after each use. According to Drexel's Program Description to AAALAC "If charcoal canisters are used for scavenging anesthetic waste gas, the research lab must weigh the canisters after each use and dispose of used canisters based on the manufacturers recommendations."	Minor	Please record the waste gas scavenger before and after each use	1 week

A3222-R



Initial Report of Noncompliance

By: Neara Gopen

Time: 2:16pm Date: 11-19-18 (b) (6) Name of Person reporting: I Acure Cham' Telephone #: (b) (6) Fax #: Email: Name of Institution: Orexel University Assurance number: A3222-01 Did incident involve PHS funded activity? _____ SRO1 MH 85666 Funding component: Was funding component contacted (if necessary): ____ two different blue performed mayon survival surgery is robert What happened? without aspesis of: no mast, notice glove net vising bead steinlight sti SAJAAA cours Species involved: Personnel involved: roseand gene met Dates and times: Animal deaths:

Projected plan and schedule for correction/prevention (if known):

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY Case #_____