



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE  
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:

Office of Laboratory Animal Welfare  
Division of Assurances  
6700B Rockledge Drive, Suite 2500, MSC 6910  
Bethesda, Maryland 20892-6910  
Home Page: <http://grants.nih.gov/grants/olaw/olaw.htm>

FOR EXPRESS MAIL:

Office of Laboratory Animal Welfare  
Division of Assurances  
6700B Rockledge Drive, Suite 2500  
Bethesda, Maryland 20817  
Telephone: (301) 496-7163

November 19, 2019

Reference Assurance: D16-00167  
(A3260-01)

Heidi Aronin, MPA  
Senior Vice President and Chief Administrative Officer  
State University of New York Downstate Medical Center  
450 Clarkson Avenue, MSC#112  
Brooklyn, NY 11203

Dear Ms. Aronin,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your July 22, 2019 letter received by OLAW on July 29, 2019 providing updated information regarding the State University of New York Downstate Medical Center's animal care and use program per OLAW's request of May 7, 2019 subsequent to OLAW's September 27, 2018 site visit.

On behalf of the Office of Laboratory Animal Welfare (OLAW), I would like to thank you for providing the requested information detailing the updates to your animal care and use program. We recognize your admirable team effort and commitment to a successful animal care and use program and compliance with the PHS Policy.

We wish you continued success with your program and invite you and your staff to contact us at any time if you have questions.

Sincerely,

11/19/2019

X Eileen M. Morgan

Signed by: Eileen M. Morgan -A  
Eileen M. Morgan  
Director, Division of Assurances  
Office of Laboratory Animal Welfare, NIH

Cc: Douglas S.F. Ling, PhD, IACUC Chair  
Julie Sharp, DVM, Director, Office of Animal Welfare  
Brent Morse, DVM, Director, Division of Compliance Oversight, OLAW



SUNY  
**DOWNSTATE**  
Medical Center

University Hospital of Brooklyn  
College of Medicine  
School of Graduate Studies  
School of Public Health  
College of Nursing  
College of Health Related Professions

July 22, 2019

Eileen M. Morgan  
Director, Division of Assurances  
Office of Laboratory Animal Welfare, NIH  
6700B Rockledge Drive  
Suite 2500, MSC 6910  
Bethesda, Maryland 20892-7982

Reference: D16-00167 (A3260-01)

Dear Ms. Morgan,

The additional information requested in your May 7, 2019 memo is summarized below. Please let us know if additional information is needed to resolve these items.

- 1) It was noted that some rats were singly housed because the animals were bigger than appropriate cage parameters for pairs as indicated by the *Guide for the Care and Use of Laboratory Animals (Guide)*. Lack of proper sized caging is not an acceptable justification for lack of social housing.

2019-01 Response:

*Rats will be socially housed according the Guide and the IACUC's policy for Social Housing. Rats will not be singly housed due to lack of proper sized caging based upon parameters within the Guide.*

May 7, 2019 OLAW Request:

Please provide further information on the housing available for large rats and the status of the resolution for the rats that were in house at the time of the site visit (if still present) and for those currently housed.

2019-07 Response: *The number of large rats in the vivarium is dynamic and regularly fluctuates in number. The rats noted at the time of the site visit are no longer present as, when labs were queried, were not needed for study and, hence, euthanized. However, to accommodate the housing needs of larger rats going forward, ten 20" x 16" x 8.5" polycarbonate cage bottoms for rats and guinea pigs, in addition to required ancillary accessories (stainless steel wire bar lids, water bottles, stoppers, card holders, and sipper tubes), were ordered from Ancare this month. Based on past maximum number of large rats, this number of cages will allow us to both co-house large rats or house them singly, where scientifically justified, and be compliant with space recommendations as detailed in the Guide for the Care and Use of Laboratory Animals.*



- 2) Provide further information on how apparatus and equipment in the investigator labs is sanitized, specifically for equipment in (b) (4)

2019-01 Response:

The hypo/hyperoxia chambers within the animal facility (such as (b) (4)) are disinfected with Rescue® between experimental groups, usually every 2-4 weeks. Animals are housed in cages which are placed within the chambers. The housing cages are changed, washed, and disinfected at least weekly according to DCM SOP. Animals are not housed outside of the animal facility. Other experimental apparatus and equipment within investigator laboratories used for non-surgical procedures are routinely sanitized with agents such as Rescue®, typically between uses, groups of animals, or experiments to minimize impact to behavior assessments.

May 7, 2019 OLAW Request:

Please provide further information on how the IACUC oversees this activity to ensure that sanitation occurs.

2019-07 Response:

During post-approval monitoring sessions and/or IACUC semi-annual site visits, the IACUC and/or OAW visually confirm equipment is clean, confirm the presence of in-date sanitation product (e.g., Rescue ®) or discuss the need for it if not present, and have personnel demonstrate or describe their sanitation process and practices.

- 3) Evaluate the sole use of enviro-dry as enrichment for rats; encourage the use of more species appropriate enrichment for rats. Consider the use of multiple nestlets for mouse enrichment so that mice can form nests as demonstrated in cages with multiple nestlets; Guide, page 43, "Animals should be provided with adequate resources for thermoregulation (nesting material, shelter) to avoid cold stress.

2019-01 Response:

**Rats:** After reaching out to all investigators using rats to confirm that additional enrichment was not contraindicated for their research, a list was made for additional items that could be included in rat cages for enrichment. This list was shared with the caretaker staff. Additional types of enrichment include nylabones, wood blocks, sticks, and tunnels. A SOP on rodent enrichment was also written and is being implemented as part of the larger SOP project noted above.

**Mice:** Singly housed mice will be provided at least two nestlets and/or a hut for both social enrichment and for thermoregulation. Mice who are co-housed will receive at least one nestlet. A SOP on rodent enrichment was also written and is being implemented as part of the larger SOP project noted above.

May 7, 2019 OLAW Request:

Please provide the timeline for the training of relevant personnel and implementation for this SOP.



2019-07 Response: The existing enrichment SOP was revised to include additional information for rats and singly housed mice. While staff were immediately trained on this, the official SOP was not implemented until July 9<sup>th</sup> at which time the staff were re-trained on this SOP during a staff meeting.

- 4) Follow-up with investigators on the appropriate use of the single housed cage cards which were in place throughout the facilities without providing any detail as to why the animals were being singly housed.

2019-01 Response: The SOP on Singly Housed Rodents was updated to clarify who is responsible for follow-up with investigators when no detail is provided on the card. The process requires veterinary care staff to follow-up with investigators and then verify the reason on an IACUC-approved list for single housing when applicable. If there is no response from investigators, they will be reported to the SUNY Downstate Office of Animal Welfare where additional action will be taken.

May 7, 2019 OLAW Request:

Please provide the timeline for the training of relevant personnel and implementation for this SOP.

2019-07 Response: The revised SOP was implemented on November 1, 2018. Prior to implementation Veterinary Technician staff and Animal Caretaker staff were provided pertinent information regarding their specific roles in the SOP during their respective staff meetings. Specifically, staff were advised to look for singly housed rodents in cages without the lavender "Singly Housed Rodent" card or cages with cards that did not have a valid reason checked off and report these violations to the Veterinary Technician responsible for rounds on that day. The Veterinary Technician staff were also trained to consult the IACUC list for protocols approved for single housing and to reach out to Principal Investigators to give them a chance to become compliant.

- 5) Develop and implement a communication mechanism for centralized access of sick animal information available to the veterinarian and other key animal program personnel to ensure timely provision of adequate veterinary care and for tracking and follow-up of animal health issues.

2019-01 Response: The current process for communication involves a spreadsheet that is emailed to the Veterinary Care team and to the Attending Veterinarian. In order to make real-time information available to the veterinarian and other key animal program personnel, an online database has been developed to capture sick animal information. This online database is available 24/7, is accessible from anywhere there is internet access, captures pertinent disposition and progress data, and makes automatic assignments via email. This system will enable staff to provide timely responses as well





SUNY  
**DOWNSTATE**  
Medical Center

University Hospital of Brooklyn  
College of Medicine  
School of Graduate Studies  
School of Public Health  
College of Nursing  
College of Health Related Professions

*as improve tracking and follow-up of animal health issues. The plan is to make this database live on February 11<sup>th</sup> after training.*

May 7, 2019 OLAW Request:

Please provide the timeline for the training of relevant personnel and implementation for this SOP.

2019-07 Response: *Staff were trained on February 1<sup>st</sup> on the use of this online database. The Administrator made additional adjustments to the electronic database based on Veterinary Technician feedback provided during a one-week trial run beginning February 4<sup>th</sup>. The system went live and has been in use since February 11<sup>th</sup>. The change in the format of data capture did not require a change in the SOP.*

Best,

(b) (6)

Heidi J. Aronin, MPA  
Institutional Official



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May 7, 2019

Reference Assurance: D16-00167  
(A3260-01)

Heidi Aronin, MPA  
Senior Vice President and Chief Administrative Officer  
State University of New York Downstate Medical Center  
450 Clarkson Avenue, MSC#112  
Brooklyn, NY 11203

Dear Ms. Aronin,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of Appendix A with your Annual Report to OLAW providing updated information regarding the State University of New York Downstate Medical Center's animal care and use program per OLAW's request of October 4, 2018.

On behalf of this Office, we would like to thank you for providing the detailed account of the actions taken by the institution to further enhance a quality program. We commend you and your team's efforts in upgrading standard operating procedures and processes to ensure compliance with all applicable regulations, policies, and standards.

For the items described below, we request updated information be provided to OLAW.

- 1) It was noted that some rats were singly housed because the animals were bigger than appropriate cage parameters for pairs as indicated by the *Guide for the Care and Use of Laboratory Animals (Guide)*. Lack of proper sized caging is not an acceptable justification for lack of social housing.

Response: Rats will be socially housed according to the *Guide* and the IACUC's policy for Social Housing. Rats will not be singly housed due to lack of proper sized caging based upon parameters within the *Guide*.

Please provide further information on the housing available for large rats and the status on the resolution for the rats that were in house at the time of the site visit (if still present) and for those currently housed.

- 2) Provide further information on how apparatus and equipment in the investigator labs is sanitized, specifically for equipment in (b) (4)

Response: Included in the response was an explanation that equipment used for non-surgical procedures is *routinely* sanitized, *typically* between uses, groups of animals, or experiments to minimize impact to behavior assessment.

Please provide further information on how the IACUC oversees this activity to ensure that sanitation occurs.

- 3) Evaluate the sole use of enviro-dry as enrichment for rats; encourage the use of more species appropriate enrichment for rats. Consider the use of multiple nestlets for mouse enrichment so that mice can form nests as demonstrated in cages with multiple nestlets; *Guide*, page 43, "Animals should be provided with adequate resources for thermoregulation (nesting material, shelter) to avoid cold stress."

Response: Rats: After reaching out to all investigators using rats to confirm that additional enrichment was not contraindicated for their research, a list was made for additional items that could be included in rat cages for enrichment. This list was shared with the caretaker staff. Additional types of enrichment include nylabones, wood blocks, sticks, and tunnels. A SOP on rodent enrichment was also written and is being implemented as part of the larger SOP project noted above.

Please provide the timeline for the training of relevant personnel and implementation for this SOP.

- 4) Follow-up with investigators on the appropriate use of the single housed cage cards which were in place throughout the facilities without providing any detail as to why the animals were being singly housed.

Response: The SOP on Singly Housed Rodents was updated to clarify who is responsible for follow-up with investigators when no detail is provided on the card. The process requires veterinary care staff to follow-up with investigators and then verify the reason on an IACUC-approved list for single housed animals when applicable. If there is no response from investigators, they will be reported to the SUNY Downstate Office of Animal Welfare where additional action will be taken.

Please provide the timeline for the training of relevant personnel and implementation for this SOP.

- 5) Develop and implement a communication mechanism for centralized access of sick animal information available to the veterinarian and other key animal program personnel to ensure timely provision of adequate veterinary care and for tracking and follow-up of animal health issues.

Response: The current process for communication involves a spreadsheet that is emailed to the Veterinary Care team and to the Attending Veterinarian. In order to make real-time information available to the veterinarian and other key animal program personnel, an online database has been developed to capture sick animal information. This online database is available 24/7, is accessible from anywhere there is internet access, captures pertinent disposition and progress data, and makes automatic assignment via email. This system will enable staff to provide timely responses as well as improve tracking and follow-up of animal health issues. The plan is to make this database live on February 11<sup>th</sup> after training.

Please provide the timeline for the training of relevant personnel and implementation for this database system.

Please provide the updated information to OLAW by July 31, 2019. Thank you for your attention to this matter. Please don't hesitate to contact us should you have any questions.

Sincerely

(b) (6)

Eileen M. Morgan  
Director, Division of Assurances  
Office of Laboratory Animal Welfare, NIH

Cc: Douglas S.F. Ling, PhD, IACUC Chair  
Julie Sharp, DVM, Director, Office of Animal Welfare  
Brent Morse, DVM, Director, Division of Compliance Oversight, OLAW

Obtained by Rise for Animals. Uploaded 08/26/2020

Retrieved from Animal Research Laboratory Overview (ARLO)

Appendix A – Annual Report to OLAW  
SUNY Downstate Medical Center D16-00167 (A3260-01)  
Reporting Period: 1/1/2018 – 12/31/2018

Eileen M. Morgan  
Director, Division of Assurances  
Office of Laboratory Animal Welfare, NIH  
6700B Rockledge Drive  
Suite 2500, MSC 6910  
Bethesda, Maryland 20892-7982

Dear Ms. Morgan,

Thank you and your site visit team members for their thorough assessment of our animal research program. We appreciate the feedback provided to our program including the commendations provided to various groups and the specific items noted to enhance our program. Please find the requested information for those items noted during the exit briefing below.

- 1) For mouse breeding colonies, animals born should be accounted for on some protocol at the point after birth when animals are first manipulated or when the cage is changed and the pups can be accurately counted. It is not clear that the mouse numbers counted at birth are being tracked in a manner which ensures that the number of mice born is being captured on some protocol.

Response: *The wean form has been revised to capture pre-weanlings that have been euthanized. We are monitoring use and completion of this form. This will also require modification of our electronic system to capture this information. We expect full implementation by the end of March 2019.*

- 2) Establish a mechanism to ensure that the IACUC is aware that deficiencies have been resolved. The correction schedule of some deficiencies identified in the semi-annual reports is long-standing due to the nature of the required corrective measures. While tracked at the Office of Animal Welfare, corrective actions should be documented in the IACUC records.

Response: *The Office of Animal Welfare tracks resolution of all site visit deficiencies until resolved. Effective with the fall 2018 IACUC semi-annual site visits, during the monthly IACUC meetings, members receive a summary of deficiencies to be corrected and those that were corrected since the previous meeting until all deficiencies were resolved. This is documented in the IACUC records and will be implemented each semi-annual site visit cycle unless the IACUC determines a different mechanism for communicating and documenting the information.*

- 3) It was noted that some rats were singly housed because the animals were bigger than appropriate cage parameters for pairs as indicated by the *Guide for the Care and Use of Laboratory Animals (Guide)*. Lack of proper sized caging is not an acceptable justification for lack of social housing.

Response: *Rats will be socially housed according the Guide and the IACUC's policy for Social Housing. Rats will not be singly housed due to lack of proper sized caging based upon parameters within the Guide.*



Appendix A – Annual Report to OLAW  
SUNY Downstate Medical Center D16-00167 (A3260-01)  
Reporting Period: 1/1/2018 – 12/31/2018

- 4) Evaluate the process for review of SOPs. Animal program SOPs should be reviewed at least every 3 years. Many of the current SOPs observed only cited a revised date, often greater than 3 years.

*Response:* A new policy was implemented creating a process for reviewing SOPs on a regular basis, at least every three years. As part of this implementation a review and revisions (if necessary) of all policies has been underway. We are currently in the last phase of this process with expected completion by April 2019.

- 5) Provide additional information on the organizational structure for the management of the animal facility as well as information on the training program and certification level for the animal care management team, animal care supervisors and animal care staff.

*Response:* Below please find a revised organization chart (page 5) and a table showing the experience and certification levels for the staff. We have recently decided to implement a new method for training staff based on the AALAS certification topic areas. This will require that a new topic be covered each month and training be provided on that topic.

FULL/PART-TIME	TITLE	EDUCATION	YEARS OF ANIMAL EXPERIENCE
FULL	OR MANAGER & VET TECH SUPERVISOR	ASSOCIATE OF APPLIED SCIENCE NYS VET TECH LICENSE	25
FULL	VETERINARY TECHNICIAN	ASSOCIATE OF APPLIED SCIENCE; LATG CERTIFICATION; NYS VET TECH LICENSE	14
FULL	VETERINARY TECHNICIAN	ASSOCIATE OF APPLIED SCIENCE	17
FULL	FACILITY SUPPORT ASSISTANT	HIGH SCHOOL	30
FULL	FACILITY MANAGER	BACHELOR OF ARTS; ASSOCIATE OF APPLIED SCIENCE; RLATG CERTIFICATION	35
FULL	HUSBANDRY SUPERVISOR	HIGH SCHOOL; ALAT CERTIFICATION	10
FULL	SR. LAB ANIMAL CARETAKER	HIGH SCHOOL	30
FULL	SR. LAB ANIMAL CARETAKER	HIGH SCHOOL	14
FULL	SR. LAB ANIMAL CARETAKER	INT'L BACC IN SCIENCE	27
FULL	SR. LAB ANIMAL CARETAKER	ASSOCIATE OF APPLIED SCIENCE	25
FULL	SR. LAB ANIMAL CARETAKER	BACHELOR OF ARTS	15
FULL	LAB ANIMAL CARETAKER	HIGH SCHOOL	15
FULL	LAB ANIMAL CARETAKER	HIGH SCHOOL	7
FULL	LAB ANIMAL CARETAKER	HIGH SCHOOL	8
FULL	LAB ANIMAL CARETAKER	HIGH SCHOOL	8
FULL	LAB ANIMAL CARETAKER	HIGH SCHOOL	9
FULL	LAB ANIMAL CARETAKER	HIGH SCHOOL; CERTIFIED ELECTRICIAN	7
FULL	LAB ANIMAL CARETAKER	HIGH SCHOOL	5
FULL	LAB ANIMAL CARETAKER	HIGH SCHOOL	19
FULL	LAB ANIMAL CARETAKER	HIGH SCHOOL	11

- 6) Provide further information on how apparatus and equipment in the investigator labs is sanitized, specifically for equipment in (b) (4)

Response:

The hypo/hyperoxia chambers within the animal facility (such as (b) (4)) are disinfected with Rescue® between experimental groups, usually every 2-4 weeks. Animals are housed in cages which are placed within the chambers. The housing cages are changed, washed, and disinfected at least weekly according to DCM SOP. Animals are not housed outside of the animal facility. Other experimental apparatus and equipment within investigator laboratories used for non-surgical procedures are routinely sanitized with agents such as Rescue®, typically between uses, groups of animals, or experiments to minimize impact to behavior assessments.

- 7) Evaluate the sole use of enviro-dry as enrichment for rats; encourage the use of more species appropriate enrichment for rats. Consider the use of multiple nestlets for mouse enrichment so that mice can form nests as demonstrated in cages with multiple nestlets; Guide, page 43, "Animals should be provided with adequate resources for thermoregulation (nesting material, shelter) to avoid cold stress.

Response:

Rats: After reaching out to all investigators using rats to confirm that additional enrichment was not contraindicated for their research, a list was made for additional items that could be included in rat cages for enrichment. This list was shared with the caretaker staff. Additional types of enrichment include nylabones, wood blocks, sticks, and tunnels. A SOP on rodent enrichment was also written and is being implemented as part of the larger SOP project noted above.

Mice: Singly housed mice will be provided at least two nestlets and/or a hut for both social enrichment and for thermoregulation. Mice who are co-housed will receive at least one nestlet. A SOP on rodent enrichment was also written and is being implemented as part of the larger SOP project noted above.

- 8) Follow-up with investigators on the appropriate use of the single housed cage cards which were in place throughout the facilities without providing any detail as to why the animals were being singly housed.

Response: The SOP on Singly Housed Rodents was updated to clarify who is responsible for follow-up with investigators when no detail is provided on the card. The process requires veterinary care staff to follow-up with investigators and then verify the reason on an IACUC-approved list for single housing when applicable. If there is no response from investigators, they will be reported to the SUNY Downstate Office of Animal Welfare where additional action will be taken.

- 9) Declutter, (boxes and old equipment), clean, and sanitize the non-survival surgery suite. Develop and implement an SOP and schedule for regular cleaning of this area.

Response:

The non-survival surgery suite was immediately decluttered, cleaned and sanitized. It is routinely cleaned and sanitized monthly and after each use.

- 10) Implement a testing mechanism for air flow and temperature for non-human primate testing chambers to ensure comfort and safety of the animals.

Response:

*Animals are continuously monitored by video camera while within the testing chambers for signs of distress. The testing chambers have multiple openings, including several doors on three sides of the chamber, a large rectangle with visual screen (with space around the periphery of the screen) on the fourth side, and a large hole on the top to accommodate tubing and cables needed within the testing chamber. All of these openings allow for varying degrees of air exchange and ventilation. Doors to the chamber are opened to the room at least hourly when in use.*

*Additionally, the PI installed an indoor/outdoor hygro-thermometer to monitor the temperature and humidity within the testing chamber as well as the room temperature. The lab continuously monitors the temperature and humidity levels from the hygro-thermometer when the chamber is in use and maintains documentation of the levels. These records are available for review during IACUC semi-annual site visits, post-approval monitoring sessions, or at the request of the veterinary staff. To ensure the comfort and safety of the animals, testing will stop and doors opened until the chamber temperature returns to room temperature if there is a differential temperature increase of 2°C (3.6°F) within the chamber, relative to the room temperature. If this becomes a common occurrence, flexible tubing from the hole in the top of the chamber to the exhaust vent and an exhaust duct anemometer will be installed to increase passive air exchange and assess.*

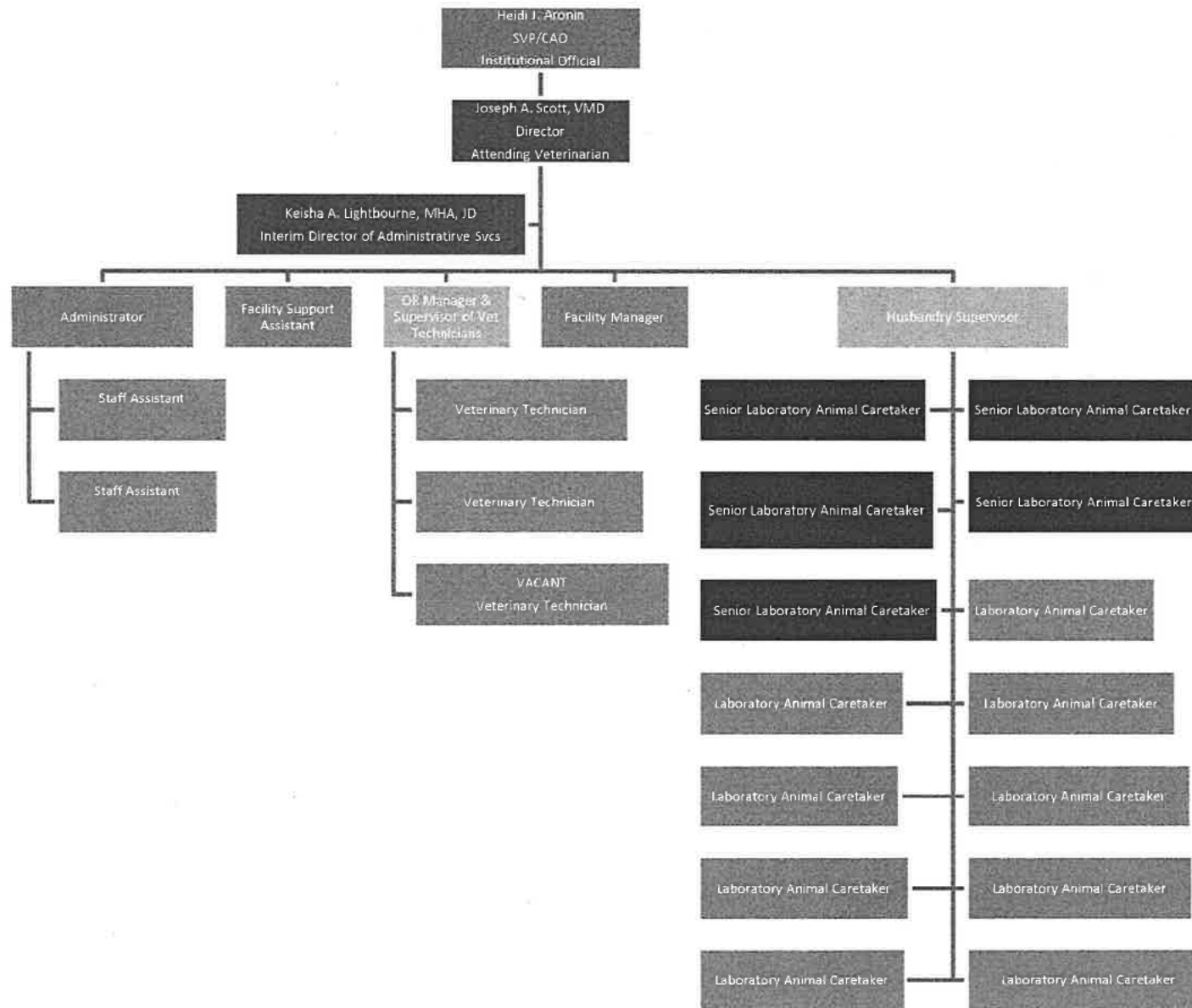
- 11) Review and update information included on the color-coded sick animal cage card to ensure consistency and accuracy in identifying the appropriate location of the cage/animal.

Response: *The sick animal cage card has been updated to include additional information about the location of the cage/animal in the event that the card gets separated from the cage. In addition, the online database (see #12 below) has a field to capture this information as well.*

- 12) Develop and implement a communication mechanism for centralized access of sick animal information available to the veterinarian and other key animal program personnel to ensure timely provision of adequate veterinary care and for tracking and follow-up of animal health issues.

Response: *The current process for communication involves a spreadsheet that is emailed to the Veterinary Care team and to the Attending Veterinarian. In order to make real-time information available to the veterinarian and other key animal program personnel, an online database has been developed to capture sick animal information. This online database is available 24/7, is accessible from anywhere there is internet access, captures pertinent disposition and progress data, and makes automatic assignments via email. This system will enable staff to provide timely responses as well as improve tracking and follow-up of animal health issues. The plan is to make this database live on February 11<sup>th</sup> after training.*

**Appendix A – Annual Report to OLAW**  
**SUNY Downstate Medical Center D16-00167 (A3260-01)**  
**Reporting Period: 1/1/2018 – 12/31/2018**



January 31, 2019

Page 5 of 5





DEPARTMENT OF HEALTH & HUMAN SERVICES

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PUBLIC HEALTH SERVICE  
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6700B Rockledge Drive, Suite 2500  
Bethesda, Maryland 20817  
Telephone: (301) 496-7163

October 4, 2018

Reference Assurance: D16-00167 (A3260-01)

Heidi Aronin, MPA  
Senior Vice President and Chief Administrative Officer  
State University of New York Downstate Medical Center  
450 Clarkson Avenue, MSC#112  
Brooklyn, NY 11203

Dear Ms. Aronin,

On behalf of the Office of Laboratory Animal Welfare (OLAW), I would like to thank you and your staff for the hospitality extended to us during the OLAW Division of Assurances September 27, 2018, site visit evaluating the State University of New York (SUNY) Downstate Medical Center's animal care and use program. This visit was part of OLAW's ongoing program to review the adequacy and accuracy of institutional compliance with the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (Policy) as described in Animal Welfare Assurances of PHS-supported institutions.

It was a pleasure meeting with you and your leadership team during our visit. We appreciate you providing us with the documents that we requested and for the time spent by all personnel who participated in the site visit.

The animal program staff we met during our visit were notably dedicated and engaged in the program with clear administrative support from you, the Institutional Official. We would like to thank Dr. Julie Sharp for her assistance with planning and logistics. We especially appreciated the forthright sharing of information by all program personnel. The site visitors observed a team approach for oversight of the animal care and use program.

IACUC record keeping and documentation were noted to be thorough and complete; protocols observed appeared to be efficiently managed and reviewed in a timely manner. It was evident in our interaction with the IACUC that members were engaged and committed to fulfilling their roles and responsibilities seriously, most notably the non-affiliated and the non-scientific member. An effective policy was in place for handling overcrowded rodent cages with an incentive plan of charging the investigator for the service and having the Division of Comparative Medicine personnel separate cages after a 24 notification to alleviate overcrowding.

Good program documentation was noted with thorough and complete IACUC records as well as animal room records. The central rodent housing and procedure area was clean, organized, well managed and used by multiple investigators on a regular basis. The CO<sub>2</sub> euthanasia chambers for rats and mice were appropriately labeled with clear instruction for investigators and designed with tamper-proof flow valves.

As noted in the exit briefing, we indicated areas which would benefit from enhanced attention in order to improve the overall program. Please provide responses to the following:

- 1) For mouse breeding colonies, animals born should be accounted for on some protocol at the point after birth when animals are first manipulated or when the cage is changed and the pups can be accurately counted. It is not clear that the mouse numbers counted at birth are being tracked in a manner which ensures that the number of mice born is being captured on some protocol.
- 2) Establish a mechanism to ensure that the IACUC is aware that deficiencies have been resolved. The correction schedule of some deficiencies identified in the semi-annual reports is long-standing due to the nature of the required corrective measures. While tracked at the Office of Animal Welfare, corrective actions should be documented in the IACUC records.
- 3) It was noted that some rats were singly housed because the animals were bigger than appropriate cage parameters for pairs as indicated by the *Guide for the Care and Use of Laboratory Animals (Guide)*. Lack of proper sized caging is not an acceptable justification for lack of social housing.
- 4) Evaluate the process for review of SOPs. Animal program SOPs should be reviewed at least every 3 years. Many of the current SOPs observed only cited a revised date, often greater than 3 years.
- 5) Provide additional information on the organizational structure for the management of the animal facility as well as information on the training program and certification level for the animal care management team, animal care supervisors and animal care staff.
- 6) Provide further information on how apparatus and equipment in the investigator labs is sanitized, specifically for equipment in (b) (4)
- 7) Evaluate the sole use of enviro-dry as enrichment for rats; encourage the use of more species appropriate enrichment for rats. Consider the use of multiple nestlets for mouse enrichment so that mice can form nests as demonstrated in cages with multiple nestlets; *Guide*, page 43, "Animals should be provided with adequate resources for thermoregulation (nesting material, shelter) to avoid cold stress.
- 8) Follow-up with investigators on the appropriate use of the single housed cage cards which were in place throughout the facilities without providing any detail as to why the animals were being singly housed.
- 9) Declutter, (boxes and old equipment), clean, and sanitize the non-survival surgery suite. Develop and implement an SOP and schedule for regular cleaning of this area.
- 10) Implement a testing mechanism for air flow and temperature for non-human primate testing chambers to ensure comfort and safety of the animals.
- 11) Review and update information included on the color-coded sick animal cage card to ensure consistency and accuracy in identifying the appropriate location of the cage/animal.

- 12) Develop and implement a communication mechanism for centralized access of sick animal information available to the veterinarian and other key animal program personnel to ensure timely provision of adequate veterinary care and for tracking and follow-up of animal health issues.

Please provide the updated information regarding the items listed above with your 2018 Annual Report, due to OLAW by January 31, 2019.

Thank you once again for hosting the OLAW site visit team. Feel free to contact us should you have any questions.

Sincerely,

10/4/2018

X Eileen M. Morgan

Signed by: Eileen M. Morgan -A

Eileen M. Morgan  
Director, Division of Assurances  
Office of Laboratory Animal Welfare, NIH

cc: Douglas S.F. Ling, PhD, IACUC Chair  
Julie Sharp, DVM, Director, Office of Animal Welfare  
Brent Morse, DVM, Director, Division of Compliance Oversight, OLAW



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE  
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FOR US POSTAL SERVICE DELIVERY:

Office of Laboratory Animal Welfare  
Division of Assurances  
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Suite 2500, MSC 6910  
Bethesda, Maryland 20892-7982  
Home Page: <http://grants.nih.gov/grants/olaw/olaw.htm>

FOR EXPRESS MAIL:

Office of Laboratory Animal Welfare  
Division of Assurances  
6700B Rockledge Drive, Suite 2500  
Bethesda, Maryland 20817  
Telephone: (301) 496-7163  
Facsimile: (301) 402-7065

September 13, 2018

Reference Assurance: D16-00167 (A3260-01)

Heidi Aronin, Ph.D.  
Senior Vice President and Chief Administrative Officer  
State University of New York Downstate Medical Center  
450 Clarkson Avenue, MSC#112  
Brooklyn, NY 11203

Dear Dr. Aronin,

On behalf of the Office of Laboratory Animal Welfare (OLAW) I am writing to inform you that we are planning a visit to State University of New York Health Science Downstate Medical Center on September 27, 2018, per section V.C. of the Public Health Service (PHS) Policy on the Humane Care and Use of Laboratory Animals (Policy). The site visitors will be myself, OLAW, Dr. Brent Morse, DVM, Director, Division of Compliance Oversight, OLAW, Dr. Neera Gopee, Veterinary Medical Officer, OLAW, and Ms. Doreen Bartlett, Senior Assurance Officer, Division of Assurances, OLAW. We are interested in seeing the animals housed and reviewing relevant records. Please note that this is not a site visit for cause, but rather it is part of our ongoing program to review the adequacy and the accuracy of institutional compliance with the PHS Policy as described in the Animal Welfare Assurance of PHS supported institutions. We request access to all animal activity areas.

Please have the following documents available for review:

- The last two semiannual program review and facility inspection reports.
- All communications from your last AAALAC Program Evaluation for Accreditation.
- The USDA reports from 2015 to the present.
- The minutes of the three most recent IACUC meetings.
- Standard Operating Procedures relevant to husbandry, enrichment, anesthesia and social housing.
- Any IACUC approved departures to the provisions of the *Guide for the Care and Use of Laboratory Animals* and the USDA Animal Welfare Regulations.
- A list of all animal use protocols and representative samples of protocols.
- Any other relevant institutional animal care and use program documents.

We would like to meet with you, your IACUC Chair and/or a representative of your animal care and use committee, the institutional veterinarian, and key members of your animal care and use program, tour the facilities and laboratories holding animals, and look at relevant paperwork. Please contact me regarding a proposed agenda for a visit beginning at approximately 8:00 or 8:30 a.m. on Thursday September 27, 2018, your facility entry requirements and directions to an initial meeting site.



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Additionally, please provide a current facility and species inventory form. Please feel free to contact me at 301-451-0384 and we can discuss the entry requirements and the plan for OLAW's visit.

Sincerely,

X  (b) (6)  
Eileen M. Morgan

Eileen M. Morgan  
Director, Division of Assurances  
Office of Laboratory Animal Welfare, NIH

Cc: Dr. Douglas Ling, IACUC Chair