



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  
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

March 16, 2020

Re: Assurance A3045-01 (D16-00024)

Sheila Vrana, PhD  
Associate Dean for Research  
The Pennsylvania State University  
College of Medicine, Hershey Medical Center  
500 University Drive, PO Box 850  
Hershey, PA 17033

Dear Dr Vrana,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your letter of January 21, 2020, providing updated information regarding the Pennsylvania State University, College of Medicine, Hershey Medical Center's animal care and use program per OLAW's request of December 5, 2019.

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

We commend you for your efforts and commitment contributing to a successful program of animal care and use and in establishing an overall culture of compliance.

Sincerely,

3/16/2020

X Eileen M. Morgan

Eileen M. Morgan

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

cc:

Neil Christensen, PhD, IACUC Chair  
Dr. Brent Morse, DVM, Acting Director, Division of Compliance Oversight

January 21, 2020

Eileen Morgan  
Director, Division of Assurances  
Office of Laboratory Animal Welfare  
Division of Assurances  
6700B Rockledge Drive  
Suite 2500, MSC 6910  
Bethesda, MD 20892-6910

Re: Assurance A3045-01 (D16-00024)

Dear Ms. Morgan:

Please accept this communication in response to the findings summarized in your letter of December 5, 2019 regarding the site visit conducted November 20 – 21, 2019 by you, Dr. Brent Morse and Ms. Paula Knapp.

Let me begin by offering a special thank you to your team for taking the time to conduct this site visit. Your visit provided a thorough and objective assessment of our animal care and use program. We especially appreciate the acknowledgement of the hard work and dedication of our IACUC, veterinarians and animal care staff, and the commendations of specific program elements.

We have thoroughly reviewed your findings summarized in your letter. Below is a point-by-point summary of how we have or plan to address your findings.

1. Counting of rodent pups.

We will be adopting a process similar to the one implemented at the Penn State University – University Park campus. Research staff will be required to count rodent pups at the first manipulation of the cage. We have reintroduced our breeding log (Attachment 1) and will require research staff to maintain the log and make it available to the IACUC during semi-annual laboratory inspections. Research staff will be asked to make adjustments to their animal numbers in the electronic protocol management system (CATS) on a regular basis.

2. Mice undergoing intra-cerebral injection not provided analgesics as described in the approved protocol.

The IACUC investigated this welfare concern and determined it to be a non-compliance event. Corrective actions have been completed by the PI and laboratory members. Analgesics (carprofen) are now administered to mice for 48 hours following surgery as described in the protocol. Animals are being assessed for signs of pain following surgery. Post-operative administration of subcutaneous fluids (sterile saline) is now being recorded. Documentation of analgesic administration, saline administration and

pain assessment was verified during a laboratory inspection on January 6, 2020 by a subgroup of the IACUC.

3. IACUC approval of analgesics "as needed."

This issue was discussed at the December 20, 2019 IACUC meeting. The IACUC re-affirmed its expectation that animals will be provided analgesics following survival surgery unless scientifically justified that they be withheld. Any statement that additional analgesics will be provided "as needed" will need to be accompanied by a description of the assessment for pain including what signs will indicate pain and how frequently the animals will be assessed. The veterinary staff were alerted at their January 2, 2020 meeting to look for analgesics provided "as needed" during pre-reviews of protocols and to communicate to researchers the IACUC expectations with regards to provision of analgesics.

4. Identification of individually-housed animals with reason for single housing.

Individually-housed animals will be identified on the cage card which was modified to include check boxes to indicate the reason for single-housing. A copy of the cage card template is attached (Attachment 2).

5. Rotation of environmental enrichment items for rabbits.

Rabbits are given hay or fruity gems at least twice a week for each to enforce positive personal interaction. Additionally, rabbits are provided with objects (such as jingle ball, rattle, wood gnawing stick, kongs) to gnaw on or play with to reduce stereotypic behavior. The objects are rotated every two weeks at cage change to minimize loss of interest in the devices. The Rabbit Husbandry Room Log (Attachment 3) now includes a check box to ensure that a rabbit will not have the same object within a period of at least 6 weeks.

6. CO<sub>2</sub> euthanasia station without appropriate equipment or instructions.

The concern raised regarding the laboratory (b) (4) visited during the site visit that did not have the appropriate equipment (flow meter) for conducting CO<sub>2</sub> euthanasia was reviewed and determined to be a non-compliance by the IACUC. The appropriate flow meter was purchased and installed, instructional signage posted, and laboratory staff re-trained on CO<sub>2</sub> euthanasia. A subgroup of the IACUC visited the laboratory on January 6, 2020 and confirmed the appropriate equipment and signage.

In addition, a communication was sent to animal users reminding research laboratories who conduct CO<sub>2</sub> euthanasia that instructional signage is to be posted near the equipment. Instructional signage will be confirmed at the next semi-annual laboratory inspections.

7. Identification of animals for euthanasia.

This issue was investigated and determined to be an isolated incident. Research staff had marked several cage cards with "sac" indicating the animals were to be euthanized by animal care staff but had not completed the complementary euthanasia form. It is our policy not to euthanize animals unless we have a completed and signed euthanasia form. The research group involved in this incident was informed and retrained on the process for requesting euthanasia of animals.

8. Inconsistent use of hazards signage.

During the tour of animal facilities there were several instances where biohazard signage was posted when there was no active work involving hazards. There was another

instance where cage cards indicated active biohazard work was taking place but there was no biohazard signage posted on the isolation cubicle. We worked with the Biosafety Officer to post the appropriate signage and met with the Biosafety and Chemical Hazard officers on January 17, 2020 to review the process for posting the relevant signage depending on the hazard.

9. VVC policy inconsistent with OLAW guidance and must be updated to specify the changes that veterinarians are verifying.

The VVC policy has been updated to define specific procedures that can be verified by an authorized veterinarian under VVC, and references have been more clearly stated next to each change that qualifies for verification by a veterinarian under VVC. In addition, additional references have been included in the policy (Attachment 4). References were previously included under a separate references subsection.

10. Sanitation of automatic watering recoil hoses.

The majority of mice housed in our facilities are provided drinking water by bottle. Rats, rabbits and some large animals (swine) are provided water by automatic watering systems. We have consulted with Avidity Science (formerly Edstrom) on best practices for sanitation of the water coils which connect animal housing racks to the automatic water supply lines. Their recommendation is periodic mechanical flushing. We have a coil hose flush manifold in one of our washrooms which we plan to have serviced by Avidity in February. Going forward, we will flush coil hoses every 6 months.

11. Verification of correction of IACUC-identified deficiencies noted at semi-annual inspection.

For deficiencies that may take longer to resolve, IACUC administrators will check on a monthly basis until completion can be documented in the inspection report. Final reports will be resent to the Institutional Official and IACUC Chair when complete. Incomplete item(s) will be carried over to the next semi-annual report, at which point completion will be documented, or items will be noted as repeat deficiencies.

12. Accelerated review process not included in assurance document.

Accelerated Review has been added to the OLAW Annual Report as "Changes to the Animal Care and Use Program" (description below). Accelerated Review will be included in the Assurance at the time of next submission.

#### Accelerated Review Process

##### *Definition:*

Accelerated Review – An accelerated Review is the process for IACUC review of an animal use protocol outside a regularly scheduled monthly meeting of the IACUC. Accelerated Reviews are typically granted when a Just-in-Time (JIT) request has been made, a piece of equipment or specialized personnel are available for only a limited time period, when delay in protocol approval may result in substantial loss of animals or cause animal welfare concern. Accelerated Review is granted at the IACUC Chair's discretion.

##### *Process:*

Occasionally there is a need/desire to have an animal care and use protocol reviewed and approved by the IACUC outside of a regularly scheduled monthly IACUC meeting. Accelerated reviews are granted only under special circumstances. Typically, such circumstances include notice of grant award for an application submitted as "Just-in-Time" (JIT), limited availability of

a particular species and/or strain of animal, or limited availability of specialized equipment or specialized technical assistance that is needed to conduct a particular study.

1. If the need for an accelerated review is determined to be justified by the IACUC Chair, then the protocol, along with any supporting documents, is communicated to all IACUC members. Each member is asked to provide their recommendation (full committee review (FCR) vs. designated member review (DMR)) and any comments they may have via email or CATS IACUC (online protocol system) within a specified period of time: three (3) business days.
2. If any one member requests FCR, the protocol must be discussed at a convened meeting. A call for FCR may occur at any time during the grace period, which ends the grace period and sends the protocol to FCR.
3. If no IACUC member has requested FCR after a 3 business day period, the IACUC Chair will move forward with DMR. The IACUC Chair will designate an IACUC member(s) to serve as the designated reviewer(s). The designated reviewer(s) will collate comments submitted by any IACUC members during the review period, and will communicate those directly to the PI for the appropriate revisions/clarifications. In CATS IACUC, the "Request Clarification by Designated Reviewer" function is utilized. If there are more than one designated reviewer, they must be unanimous in their decision to approve or require modifications to secure approval, otherwise the protocol will be called to FCR.
4. Protocol review and approval will then proceed as described in our Assurance under "IACUC Review Processes and Outcomes".

13. Protocol review outcome of "tabled."

"Tabled" is an outdated term that is no longer in use and has been removed from the meeting minutes.

We are hopeful that the above responses have addressed the issues that were discussed at our Exit Briefing. We look forward to hearing that the changes and actions taken have satisfactory addressed the concerns.

Please contact me at (b) (6) if you have questions or need additional information.

Sincerely,

(b) (6)

Sheila Vrana, PhD.  
Institutional Official

cc: Dr. Ronald P. Wilson, Attending Veterinarian  
Dr. Neil Christensen, IACUC Chair  
IACUC Office



Animal Room No.: \_\_\_\_\_  
 Start Date: \_\_\_\_\_ End Date: \_\_\_\_\_  
 IACUC Protocol Number(s): \_\_\_\_\_

[illegible]

**DEFINITIONS:**

**Cross number:** Laboratory generated number that indicates generation.

**Male ID number:** Laboratory generated number that identifies the male.

**Female ID number:** Laboratory generated number that identifies the female.

**Pairing date:** Date that the male and female were placed in the cage together.

**DOB:** Date of birth of the pups.

**# of pups:** Number of pups born.

**# of pups dead (D) or euthanized (E):** Number of pups that died or were euthanized (can be indicated by "D" or "E")

**Anticipated wean date:** Date that reflects the normal weaning age for that strain.

**# of pups weaned:** Number of pups that were separated from the mother at the weaning date.

**# of pups to breed:** Number of pups that will be used for breeding.

**# of pups transferred to experimental protocol:** Number of pups that will be transferred to an experimental protocol.

**Experimental IACUC protocol #:** The protocol number for the experimental protocol to which the mice will be transferred.

**Line code:** Internal laboratory number to indicate the line of mice being produced.

<p style="text-align: center;"><b>MICROBIOLOGY H107</b></p> <p>DATE RECEIVED _____ SOURCE/PO# _____</p> <p>INVESTIGATOR _____</p> <p>SPECIES/STRAIN: _____</p> <p>SEX: _____ NUMBER OF ANIMALS IN CAGE: _____</p> <p>ID# _____ PROTOCOL : _____</p> <p>REMARKS: _____</p> <div style="border: 1px solid black; padding: 5px; margin-top: 10px; text-align: center;"> <u>Single Housed</u>  <input type="checkbox"/> IACUC-approved      <input type="checkbox"/> Vet care  <input type="checkbox"/> Cagemate used/euthanized      <input type="checkbox"/> Fighting  <input type="checkbox"/> Overcrowd compliance         </div> <p>Rev. 9/09</p>	<p style="text-align: center;"><b>MICROBIOLOGY H107</b></p> <p>DATE RECEIVED _____ SOURCE/PO# _____</p> <p>INVESTIGATOR _____</p> <p>SPECIES/STRAIN: _____</p> <p>SEX: _____ NUMBER OF ANIMALS IN CAGE: _____</p> <p>ID# _____ PROTOCOL : _____</p> <p>REMARKS: _____</p> <div style="border: 1px solid black; padding: 5px; margin-top: 10px; text-align: center;"> <u>Single Housed</u>  <input type="checkbox"/> IACUC-approved      <input type="checkbox"/> Vet care  <input type="checkbox"/> Cagemate used/euthanized      <input type="checkbox"/> Fighting  <input type="checkbox"/> Overcrowd compliance         </div> <p>Rev. 9/09</p>
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3" H x 5" W



MONTH YEAR \_\_\_\_\_

## RABBIT HUSBANDRY ROOM LOG

BUILDING ROOM NUMBER \_\_\_\_\_

Daily Tasks	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
Animal Observation																															
Environmental Monitoring	THIS FORM IS FOR USE WITH ROOMS MONITORED BY METASYS																														
Feed																															
Water																															
Pest Control																															
Daily Cleaning																															
Environmental Enrichment																															
Twice Weekly	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
Change Paper Tray Liners																															
Mop Floor																															
Clean exhaust Grill																															
Clean Sink																															
Weekly	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
Sanitize Feed Hoppers																															
Sanitize Water Bowls/Bottles																															
Weekly Cleaning																															
Every Two Weekly	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
Change Cages																															
Change Enrichment Device																															
Sanitize Room																															
Check Light Timer																															
Monthly	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
Sanitize Feed Bin																															
Sanitize Trash Can																															

Enrichment Devices: A) Jingle ball B) Rattle C) Stainless steel pacer ball D) Action ball E) Axis bone

Revised January 2020

Rabbit Husbandry Room Log



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

December 5, 2019

Re: Assurance A3045-01 (D16-00024)

Sheila Vrana, PhD  
Associate Dean for Research  
The Pennsylvania State University  
College of Medicine, Hershey Medical Center  
500 University Drive, PO Box 850  
Hershey, PA 17033

Dear Dr. Vrana,

On behalf of the Office of Laboratory Animal Welfare (OLAW) we would like to thank you and your staff for the hospitality extended to us during the OLAW Division of Assurances November 20-21, 2019 site visit of your 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).

We appreciate the time and effort put forth by you, the Institutional Official, and the many individuals we had the pleasure of meeting during the site visit. We thank those who coordinated logistics, escorted us throughout the visit, answered questions and provided documentation. We especially want to thank the Attending Veterinarian, Clinical and Resident Veterinarians, the Program Manager and Facility Supervisor, the IACUC Administrators, and IACUC Members for assisting in the site visit.

In the opening session the site visitors observed knowledgeable key program personnel with a system of good communication and a team approach to oversight of the animal care and use program. Excellent veterinary support of the animal care and use program including research support was noted. In addition, all animals observed, including rodents, large animal species and aquatics were well cared for and found to be in good health.

We noted particular program elements that were commendable including:

- The creation and implementation of the hands-on animal use training program;
- Appropriate enrichment being provided to all animal species;
- Pair housing of young rabbits which optimized social interactions of this species;
- Use of the protocol "snapshot" which provided good communication between the research personnel, veterinary personnel, animal husbandry and technical staff;

- A protocol review database system which captures all comments and questions from all reviewers in one easy to reference location;
- Thorough and organized IACUC minutes that also provide direct links to educational material from OLAW and other regulating entities;
- Use of the key control system that identifies the user for follow up and tracking of keys which is unique and impressive;
- An occupational Health and Safety Program that appears to be comprehensive; personnel are enrolled and are aware of the options available to them;
- Regular schedule of sanitation of the surgery suite, the animal rooms and cage wash areas which are conducted on an appropriate schedule and documented on the room log;
- Considering the apparent age of the facilities the operations regarding animal care and research appear to function adequately;

Some areas for which we require additional information include the following:

- It was not evident that accounting for rodent pups is consistent with OLAW guidance. 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. Animal numbers should be tracked in a manner that ensures that the number of mice born is being captured and deducted from approved animal numbers for each IACUC protocol.  
Accounting for pups more frequently than on an annual basis permits the IACUC to provide more responsive oversight to accurately reflect animals currently being used in the program. Establish an institutional mechanism to document and monitor rodent pups consistent with OLAW guidance;
- Animals that undergo intra-cerebral injection were documented in the lab's electronic notebook as receiving Carprofen injection post-procedure and afterwards *as needed*. No analgesics had been given after the post-procedure injection. However, the approved protocol described Carprofen as being given subcutaneous every 24 hours for a total of 48 hours and as needed thereafter. The technician described injecting subcutaneous saline on subsequent days. The protocol described the saline injections as stated by the research investigator, but there was no documentation that this occurred.
- Reconsider the IACUC approving analgesics 'as needed'. Instead state the intervals that the analgesic be administered with specific criteria documented for discontinuing administration of analgesics such as body condition scoring, mouse grimace scale or a pain index.
- Recommend identifying singly housed animals with the reason for single housing noted at the cage level;
- Although all rabbits had some form of environmental enrichment in their cage, there was no system for providing a rotation of environmental enrichment devices;
- Not all areas where CO2 euthanasia was performed exhibited proper user instructions;
- Signage was not always clear regarding animals intended for euthanasia; there was a hazard identification sign posted when no hazard was present, and hazard identification signage was absent when a hazard was in place;
- The VVC Policy is not consistent with OLAW guidance; the current policy does not provide specific changes that the veterinarian can verify, it only references general SOPs. The IACUC should define the type of procedures that it agrees can be conducted by VVC and include those specific procedures in the IACUC approved VVC Policy; (for example: methods of behavioral testing from Morris water maze to T-maze, sites of blood collection or injection sites, or tissue sources for genotyping); Include in the approved Policy the reference documents for the veterinarian to use to verify those specific changes such as the institution's drug formulary, the AVMA Guidelines for the Euthanasia of Laboratory Animals, or other appropriate reference documents;
- Establish a mechanism for sanitation of automatic watering recoil hoses;

- It was difficult to verify that deficiencies from the previous semi-annual report had been resolved because documentation was retained in different locations in the records. Develop a mechanism for documentation of resolution of deficiencies in the semi-annual report so that the committee can verify that resolution of previous issues has occurred.
- Assurance Items:
  - Accelerated review was described in IACUC minutes and SOPs but not described in the Assurance;
  - The protocol review outcome of 'tabled' is described in the IACUC minutes but not described in the Assurance.

Please provide updated information to the above items with your Annual Report due to OLAW by January 31<sup>st</sup>, 2020.

Thank you once again for your time and hospitality in hosting the OLAW site visit.

Sincerely,

(b) (6)

Eileen M. Morgan  
Director, Division of Assurances  
Office of Laboratory Animal Welfare  
National Institutes of Health

cc: IACUC Chair  
Executive Director of Research Compliance  
Attending Veterinarian  
Brent Morse, Director, Division of Compliance Oversight, NIH/OLAW



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November 6, 2019

Re: Assurance D16-00024 (#A3045-01)

Sheila Vrana, PhD  
Associate Dean for Research  
The Pennsylvania State University  
College of Medicine, Hershey Medical Center  
500 University Drive, PO Box 850  
Hershey, PA 17033

Dear Dr. Vrana,

On behalf of the Office of Laboratory Animal Welfare (OLAW) I am writing to inform you that we are planning a visit to The Pennsylvania State University, College of Medicine, Hershey Medical Center on November 20-21, 2019, 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, Dr. Brent Morse, DVM and Ms. Paula Knapp. 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.
- The USDA reports from 2015 to the present.
- The minutes of the three most recent IACUC meetings.
- All communications between the institution and AAALAC International for the last three years.
- 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 on Wednesday at approximately 8:00 or 8:30 a.m. and instructions for local parking or regional transportation, as well as directions to an initial meeting site.

Additionally please provide a current facility and species inventory form by building along with a list of procedure areas where vertebrate animal work is performed. Please feel free to contact me at 301-496-7163 and we can discuss the entry requirements and the plan for OLAW's visit.

Sincerely,

X  (b) (6)

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

cc: IACUC Chairperson  
Executive Director of Research Compliance