



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) 496-716

August 7, 2019

Reference: Animal Welfare Assurance  
D16-00086 (A3141-01)

Candice Yekel, MS  
Associate VP for Research and Director of ORP  
The Pennsylvania State University – University Park  
The 330 Building- (b) (4)  
University Park, PA 16801-7014

Dear Dr. Yekel,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of the letter dated July 31, 2019 providing updated information regarding The Pennsylvania State University's animal care and use program per OLAW's request of April 16, 2019.

On behalf of the Office of Laboratory Animal Welfare (OLAW), I would like to thank you for providing updated information regarding your animal care and use program. Dr. Morse and I thank you for providing the requested information detailing the updates to your animal care and use program processes and standard operating procedures. 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,

(b) (6)

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

cc: Robert Van Saun, DVM, PhD, IACUC Chair

(b) (6)

Brent Morse, Director, DVM, Division of Compliance Oversight, NIH/OLAW



**PennState**

Candice A. Yekel  
Associate Vice President for Research  
Director of Research Protections  
The Pennsylvania State University  
205 The 330 Building  
University Park, PA 16802

814-865-1775  
Fax: 814-863-8699  
cay3@psu.edu  
research.psu.edu/orp

July 31, 2019

Eileen M. Morgan  
Director, Division of Assurances  
Office of Laboratory Animal Welfare  
National Institutes of Health  
RKL1, Suite 360, MSC 7982  
6705 Rockledge Drive  
Bethesda, MD 20892-7982

Dear Eileen:

The Pennsylvania State University, Assurance A3141-01 would like to thank you and your site visit team for your recent review of our animal care and use program, conducted March 20-22, 2019.

Your commendations to our program were very much appreciated and shared with the various stakeholders involved in our program. Additionally, we worked closely with these same stakeholders to provide responses to the areas you had requested additional information on. Please find below your list of areas requiring more attention and our institutional response to each:

- Area: It was not evident that accounting for rodent pups is consistent with OLAW guidance. Animals born should be accounted for 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 in a timely manner from approved animal numbers on each protocol. Accounting for pups more frequently than annually allows the IACUC to provide more responsive oversight and accurately reflect animals being used in the program.
- **Response:** *The current IACUC protocol form does require the PI to list the total number of animals needed for an experiment, including those for breeding, those for research and those produced but not used for research. Each PI breeding rodents is also responsible for reporting annually on the total number of animals used in each of these categories. PI's have since been notified that these numbers must be kept up to date and will be subject to audit. They have been informed that the IACUC expects these numbers to be recorded regularly and must be based on animals counted at the point after birth when animals are first manipulated or when the cage is changed, and the pups can be accurately counted. This will be enforced by audit of records during semi-annual inspections and additional post approval monitoring.*

- Area: Re-evaluate the consistency of analgesic administration for rat protocols with cranial implants.
- **Response:** *The issue was identified between two different protocols with cranial surgery requiring two different analgesic prescriptions. After review with the Attending Veterinarian, and modification submitted and approved by the IACUC, both protocols are now consistent: Ketoprofen is administered prior to surgery; "Bupivacaine is infused locally around the incision site prior to surgery to provide local anesthesia. It may also be applied to the wound area just prior to wound closure/suturing." This will be the standard for this procedure unless better alternatives are identified, or justification is provided and approved by the IACUC.*
- Area: A ventilated rack for the guinea pigs on the influenza study was set to positive pressure when inoculated animals were present in the cages. Evaluate practices to ensure proper operation.
- **Response:** *These were new racks and at the time of the visit were functioning at first-time use. Our Animal Resource Staff believed the vendor had programmed the motors appropriately, which they had not. Once this issue was identified the settings were immediately changed. These are specialty racks and the only two of this type we have. Both are now programmed properly. If any new units are ordered they will be tested prior to use.*
- Area: The semi-annual reports should include a plan and schedule for correction of deficiencies noted. In the spring 2018 program review a deficiency was described without these components. Ensure that future IACUC minutes close the loop regarding corrections of previous deficiencies.
- **Response:** *The Penn State IACUC spring 2018 program review indicated a minor deficiency in the section "Veterinary Care, 3. Surgery," which asks if "Researchers have appropriate training to ensure good technique." Although this was noted as a minor deficiency in the spring 2018 program review, no record of resolution was found. The IACUC recognizes this gap and at a fully convened meeting on March 28, 2019 meeting, the IACUC discussed the issue and noted that it had been resolved by fall 2018. The discussion and resolution have now been documented in official IACUC meeting minutes to close the loop.*
- Area: Review the policy on animal room sanitation. Recommend ATP evaluation of surfaces (walls, floors, etc.) to ensure acceptable sanitation practices. "All components of the animal facility should be regularly cleaned and disinfected ...." Guide page 72.
- **Response:** *At a fully convened meeting of the IACUC, the Attending Veterinarian provided the IACUC a description of our current process of sanitation and described that the current process was adequate. This was based on history and performance data that sanitizing a room based on schedule rather than need would induce more stress to the animals as opposed to the benefits that would be provided to the animals if a populated room needed to be sanitized more frequently. Current practice is to sanitize a room when 1) the room is painted, or other work orders are completed that requires an empty room; 2) a study ends; and 3) bio-security (sentinel) outbreak is identified.*
- Area: Re-evaluate the SOP "Administrative/Veterinary Review and Approval of IACUC Protocols and Protocol Modifications" to specify what is meant by "Reuse of animals"

and "Custom antibody production protocols." Additionally, re-evaluate the veterinary review section to either create a VVC policy or regard the changes described for veterinary approval as clinical care and only applicable to a single animal or single group of animals.

- **Response:** A revision to the SOP "Administrative/Veterinary Review and Approval of IACUC Protocols and Protocol Modifications" now titled "Administrative Review and Approval of IACUC Protocols and Protocol Modifications" has been modified to specify the "Reuse of animals" as "the use of the same animals for unrelated experiments." This complements existing IACUC policy 11 "Reuse of Laboratory Research Animals", which further states that "in no circumstance, may animals undergoing painful, and/or distressful (Category D and/or E) procedures, be transferred to another protocol for use in additional survival, painful, and/or distressful procedures." Any case in which a protocol requests that multiple procedures that may induce substantial post-procedural pain or impairment may be conducted on a single animal must be justified by the PI and approved by the IACUC. Multiple major surgical procedures on a single animal are acceptable only if they are: included in and essential components of a single research project or proposal; scientifically justified by investigator; or necessary for clinical reasons. (Note, clinically necessary procedures do not necessarily require review and approval by the IACUC in advance of the procedure.) The IACUC understands that cost savings alone are not an adequate justification for performing multiple major survival surgical procedures. The SOP has also been updated to provide clarification on what is meant by custom antibodies and will now read "A request to purchase custom antibodies from an outside source must be reviewed. This is done using the Custom Antibody Production Protocols. This form is administratively reviewed to ensure the outside source has a project specific IACUC approval and PHS assurance, if applicable. Finally, we have removed the veterinary approval section from this SOP and have proposed a new VVC policy which will be reviewed at the August 2019 IACUC meeting.
- Area: Reevaluate current practices to consider that the IACUC enhance their oversight mechanisms of outlying locations to include video communication that document specific aspects of the study sites through the use of programs such as Facetime, Skype, etc.
- **Response:** The IACUC will now require video conferencing inspections of outlying locations in place of still photos.
- Area: Provide updates to the Animal Welfare Assurance as discussed in the exit briefing, Part III.B., Part III.D.4., Part III.D.6., and Part III.G.
- **Response:** The Penn State University Animal Welfare Assurance has been updated and submitted to OLAW, division of assurances. These updates include:
  1. Section III.B. was updated for each veterinarian to include the name of the AVMA-accredited veterinary school attended or indicate Educational Commission for Foreign Veterinary Graduates (ECFVG) or Program for the Assessment of Veterinary Education Equivalence (PAVE) and the North American Veterinary Licensing Examination (NAVLE) certification and date.
  2. Section III.D.4. was updated with the added statement indicating that there is an available option for anonymous reporting of Animal Welfare Concerns.

Eileen Morgan  
July 31, 2019  
Page 4

3. *Section III.D.6. was updated to indicate that a majority vote of the quorum present at a convened meeting is required for the FCR outcome of "require modifications to secure approval."*
4. *Section III.G. was updated to include training in "research or testing methods that minimize the number of animals required to obtain valid results and minimize animal distress" is provided to animal care staff.*

Sincerely,

(b) (6)

Candice A. Yekel  
Institutional Official

cc: J. DeRicco, IACUC Director  
M. Kennett, Attending Veterinarian  
B. Morse, Director, Division of Compliance Oversight  
(b) (6)  
R. Van Saun, IACUC Chair



**PennState**

**Candice A. Yekel**

Associate Vice President for Research  
Director of Research Protections  
The Pennsylvania State University  
205 The 330 Building  
University Park, PA 16802

814-865-1775  
Fax: 814-863-8699  
cay3@psu.edu  
research.psu.edu/orp

Date: July 30, 2019

(b) (6)

From: Candice A. Yekel, Associate Vice President for Research, Institutional Official

To: Division of Assurances, Office of Laboratory Animal Welfare, NIH

Re: Update to an existing Domestic Assurance as required following OLAW site visit

The Pennsylvania State University requests a modification to assurance D16-00086 (#A3141-01) (please see attachment). This modification is requested to update our assurance in response to a recent OLAW site visit and includes:

1. Section III.B. updated for each veterinarian to include the name of the AVMA-accredited veterinary school attended or indicate Educational Commission for Foreign Veterinary Graduates (ECFVG) or Program for the Assessment of Veterinary Education Equivalence (PAVE) and the North American Veterinary Licensing Examination (NAVLE) certification and date.
2. Section III.D.4., updated with the added statement indicating that there is an available option for anonymous reporting of Animal Welfare Concerns.
3. Section III.D.6., updated to indicate that a majority vote of the quorum present at a convened meeting is required for the FCR outcome of require modifications to secure approval.
4. Section III.G. updated of the approved Assurance, to include training in "research or testing methods that minimize the number of animals required to obtain valid results and minimize animal distress" is provided to animal care staff.

As a covered component, The Pennsylvania State University will assure we comply with the Public Health Service Policy on Humane Care and Use of Laboratory Animals and the conditions of assurance D16-00086 (#A3141-01).

If you have any questions or concerns, please contact our IACUC Program Director, Jeremy DeRicco ([jzd237@psu.edu](mailto:jzd237@psu.edu)).

Attachment: PSU 2019 PHS Modified Assurance

cc: Jeremy DeRicco, IACUC Program Director

(b) (6)



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://olaw.nih.gov>

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

February 19, 2019

Re: Assurance D16-00086 (#A3141-01)

Candice Yekel, MS  
Associate VP for Research and Director of ORP  
Pennsylvania State University – University Park  
The 330 Building (b) (6)  
University Park, PA 16801-7014

Dear Ms. Yekel,

On behalf of the Office of Laboratory Animal Welfare (OLAW) I am writing to inform you that we are planning a visit to Pennsylvania State University – University Park on March 21-22, 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, Drs. Brent Morse, DVM, DACLAM, Jane Na, DVM, Joseph Schech, DVM, DACLAM, DACVPM, 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 Tuesday 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 301-402-4325 and we can discuss the entry requirements and the plan for OLAW's visit.

Sincerely,

2/19/2019

**X** Eileen M. Morgan

---

Signed by: Eileen M. Morgan -A

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

cc: IACUC Chairperson  
Executive Director of Research Compliance