

Annual Report to OLAW

Institution: The Pennsylvania State University College of Medicine
Assurance Number: D16-00024 (A3045-01)
Reporting Period: January 1, 2019 thru December 31, 2019

This institution's Institutional Animal Care and Use Committee (IACUC), through the Institutional Official, provides this annual report to the Office of Laboratory Animal Welfare (OLAW).

I. Program Changes [Select A or B]

- ☐ A. There have been **no changes** in this institution's program for animal care and use as described in the Assurance. [Skip to Item II.]
- ☒ B. Change(s) in this institution's program for animal care and use as described in the Assurance have occurred during this reporting period. (FAQ 6)

Select all that apply:

- ☐ This institution's AAALAC accreditation status has changed (PHS Policy IV.A.2.).
- ☐ AAALAC Accredited - Category 1
- ☐ Non-Accredited - Category 2
- ☒ This institution's program for animal care and use has changed (PHS Policy IV.A.1.a-i). [Attach a full description of the changes.]
- ☐ The individual designated by this institution as the Institutional Official has changed. [Provide name, title(s), address, e-mail, phone, and fax numbers in Item V.]
- ☒ The membership of this institution's IACUC has changed. [Provide current roster of members in Item VI.]

II. Semiannual Evaluations

This IACUC has conducted semiannual evaluations of the institution's program and inspections of the institution's facilities (including satellite facilities) on the dates below. Reports of the evaluations and inspections have been submitted to the Institutional Official. The reports include any IACUC-approved departures from the Guide with a reason for each departure, any deficiencies (significant or minor) that were identified, and a plan and schedule for correction of each deficiency. [Do not provide semiannual reports unless they include a minority view.]

A. Program Evaluations

[Two dates (month/day/year) must be provided to satisfy the PHS Policy requirement that evaluations be done at 6 month intervals. If the IACUC conducted more than 2 evaluations of the program during the reporting period, please attach a list showing the dates.]

Date 1: April 22, 2019	Date 2: November 1, 2019
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B. Facility Inspections

[Two dates (month/day/year) must be provided to satisfy the PHS Policy requirement that facility inspections be done at 6 month intervals. If the IACUC conducted more than 2 inspections of each site during the reporting period, please attach a list showing the dates.]

Date 1: April 1-16, 2019

Date 2: October 7-31, 2019

III. Minority Views [Select A or B]

- [X] A. There were **no minority** views during this reporting cycle.
- [] B. Any minority views submitted by members of the IACUC regarding reports filed under PHS Policy IV.F. for this reporting cycle are attached.

IV. Signatures

IACUC Chairperson	Institutional Official
Name: Neil Christensen	Name: Sheila Vrana
Signature: (b) (6)	Signature: (b) (6)
Date: 01/21/2020	Date: 1-21-20

V. Change in Institutional Official

Name:	
Title:	Degree/Credential:
Name of Institution:	
Address: [street, city, state, zip code]	
E-mail:	
Phone:	Fax:

VI. Change in IACUC Membership [*Current roster*]

Institution: The Pennsylvania State University College of Medicine			
IACUC Contact Information			
Address: 500 University Drive, Hershey, PA 17033			
IACUC Office staff: Rachel Panas, Viola Devine			
E-mail: IACUC@pennstatehealth.psu.edu			
Phone:	(b) (6)	Fax:	
IACUC Chairperson			
Name: Neil Christensen			
Title: Professor of Pathology		Degree/Credentials: PhD	
PHS Policy Membership Requirements***: Scientist			
IACUC Roster [<i>Provide below or attach</i>]			
Name of Member/ Code*	Degree/ Credential	Position Title/ Occupational Background**	PHS Policy Membership Requirements***
Ronald Wilson	VMD, MS, DACLAM	Professor and Chairman of Comparative Medicine	Attending Veterinarian
(b) (6)			Scientist
			Scientist
			Scientist
			Veterinarian
			Scientist
			Scientist
			Nonscientist
			Nonaffiliated

* Names of members, other than the chairperson and veterinarian, may be represented by a number or symbol in this report to OLAW. Sufficient information to determine that all appointees are appropriately qualified must be provided and the identity of each member must be readily ascertainable by the institution and available to authorized OLAW or other PHS representatives upon request.

** List specific position titles for all members, including nonaffiliated (e.g., banker, teacher, volunteer fireman; not "community member" or "retired").

*** PHS Policy Membership Requirements:

<i>Veterinarian</i>	veterinarian with training or experience in laboratory animal science and medicine or in the use of the species at the institution, who has direct or delegated program authority and responsibility for activities involving animals at the institution.
<i>Scientist</i>	practicing scientist experienced in research involving animals.
<i>Nonscientist</i>	member whose primary concerns are in a nonscientific area (for example, ethicist, lawyer, member of the clergy).
<i>Nonaffiliated</i>	individual who is not affiliated with the institution in any way other than as a member of the IACUC, and is not a member of the immediate family of a person who is affiliated with the institution. This member is expected to represent general community interests in the proper care and use of animals and should not be a laboratory animal user. A consulting veterinarian may not be considered nonaffiliated.

[Note: all members must be appointed by the CEO (or individual with specific written delegation to appoint members) and must be voting members. Non-voting members and alternate members must be so identified.]

Changes to Program to be added to Assurance:

1) 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".

2) Meeting Minutes – vote to approve rather than collection of members' signatures

The Research Compliance Specialists attend all IACUC meetings to record the discussion and prepare minutes. Minutes of meetings for the semi-annual program and facilities reviews and facility/laboratory inspections are read and signed by all IACUC members indicating that the statements made are an accurate and complete reflection of the reviews and that they concur with the decisions made. Any IACUC member may also submit a minority view if they wish.

For meetings outside of semi-annual program review (e.g., protocol review meetings and specially convened meetings to address concerns or issues regarding the care and use of animals), a vote is taken at subsequent review meetings to approve meeting minutes. All IACUC members are provided an opportunity to review meeting minutes and associated documents.