

Annual Report to OLAW

Institution: Schepens Eye Research Institute
Assurance Number: D16-00112 (A3177-01)
Reporting Period: January 1, 2019 – 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: February 13, 2019 and March 6, 2019	Date 2: August 9, 2019 and September 5, 2019
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B. Facility Inspections


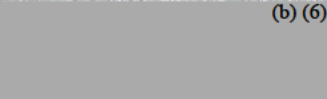
[Two dates (month/day/year) must be provided to satisfy the PHS Policy requirement that facility inspections be done at 6 month intervals. If the IACUC conducted more than 2 inspections of each site during the reporting period, please attach a list showing the dates.]

Date 1: March 11, 2019	Date 2: September 19 2019
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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: Meredith Gregory-Ksander, Ph.D.	Name: Martha Pyle Farrell
Signature:  (b) (6)	Signature:  (b) (6)
Date: 1-23-2020	Date: 23 January, 2020

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: Schepens Eye Research Institute			
IACUC Contact Information			
Address: [street, city, state, zip code]			
IACUC Office c/o Candace Beiler 20 Staniford Street Boston, MA 02114			
E-mail: (b) (6)@meei.harvard.edu			
Phone: (b) (6)		Fax:	
IACUC Chairperson			
Name: Meredith Gregory-Ksander			
Title: Associate Scientist		Degree/Credentials: Ph.D.	
PHS Policy Membership Requirements ***: Chairman/Scientific Member			
IACUC Roster [Provide below or attach]			
Name of Member/ Code*	Degree/ Credential	Position Title/ Occupational Background**	PHS Policy Membership Requirements***
(b) (6)			Scientific Member/Vice Chairman
			Scientific Member
			Scientific Member
			Scientific Member
			Scientific Member
			Scientific Member
Karen Krueger	DVM, DACLAM	Attending Veterinarian	Veterinarian
Marie Ortega	BA, CMAR, CPIA, RLATG	Director, Animal Care	Voting Member
(b) (6)			Nonaffiliated/Non-Scientific Member
			Non-Scientific Member
			Non-Voting Member
			Non-Voting Member
			Non-Voting Member

* 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.]

Change in Program – New Veterinary Verification and Consultation (VVC) Amendment Process

Section III (Institutional Program for Animal Care and Use), D (The IACUC Will):

The current Assurance states:

7. Review and approve, require modifications in (to secure approval), or withhold approval of proposed significant changes regarding the care and use of animals in ongoing activities as set forth in the PHS Policy at IV.C. The IACUC procedures for reviewing proposed significant changes in ongoing research projects are as follows:

The principal investigator (PI) initiates the review process by submitting a completed procedural amendment to the Senior IACUC Administrator who then pre-reviews the amendment to ensure that all sections are completed and answered thoroughly. The Chair, or Vice-Chair, in the absence of the Chair, then appoints at least two qualified members to review the amendment as designated member reviewers (DMR). Once these reviewers are assigned, the IACUC Office sends (by e-mail) the proposed procedural amendment along with the approved protocol to the Committee, allowing them to review the document and poll to review the revised protocol by DMR or by the full committee at the next convened meeting. The Committee has 48 hours to vote for either Designated Member Review (DMR) or Full Committee review (FCR). During the 48-hour vote, any Committee member may request to serve as an additional reviewer for the proposed amendment or may provide comments to the IACUC Office that will be provided to the designated reviewers. After 48 hours, any votes not received by any member are assumed to be for DMR. If any member votes for FCR, the vote process comes to an end and the procedural amendment will be brought to the next convened full Committee meeting. The full Committee review is conducted as described in Section III.D.6. After the 48 hours, if all votes were in favor of DMR, the Senior IACUC Administrator will e-mail the assigned reviewers (through the Chair, or Vice Chair, in the absence of the Chair) informing them that they can begin to review the document. The assigned designated reviewers will receive and review identical copies of the procedural amendment. At this time, the Senior IACUC Administrator will also forward the reviewers any comments that were received by other members during the 48-hour vote period. However, the DMR cannot be conditioned. The designated-reviewer approval has equal validity to full-committee review approval. The reviewers have 3 days to review the proposed amendment and then vote to either approve, require modifications, or request full Committee review. In addition, during this review process the designated-reviewers follow the Schepens IACUC approved policy on Minor or Significant changes to an approved protocol, to determine if an amendment is sufficient or if the submission of a new protocol is required. The Criteria used to define minor and significant changes to a protocol are summarized below. If the designated reviewers have concerns, their comments are submitted to the IACUC Office. The Senior IACUC Administrator compiles all of the comments to be sent to the PI and sends them back to the reviewers (by e-mail) to ensure that all assigned reviewers are in agreement with the comments. The reviewers have 24 hours to agree/disagree with the comments. If any member does not respond within the 24 hours, it is assumed that s/he agrees with the comments. After the 24 hours, these comments are sent (by e-mail) to the PI, who must submit a revised amendment addressing the concerns and corrections to the IACUC Office. The revised amendment is then sent back (by e-mail) to the assigned reviewers, who must approve the revisions of the amendment unanimously in order for it to be considered approved by the Committee. At any time, a designated member reviewer may request that the full Committee re-review the amendment. All procedural amendments, whether involving minor or significant changes (see below for criteria used to define minor and significant changes), go through the above submission, review and approval process, with the exception of personnel amendments.

The IACUC procedures for review of a personnel amendment to a protocol are as follows:

The principal investigator (PI) initiates the review process by submitting a completed personnel amendment to the Senior IACUC Administrator, who then reviews the personnel amendment to ensure that all sections are completed and answered thoroughly. The Senior IACUC Administrator will either provide comments back to the PI to correct and resubmit or the amendment is approved by the IACUC chair or designee.

Criteria used to define minor and significant changes to a protocol as stated in the Schepens approved policy:

Minor Changes: *In general, minor changes needing an amendment are defined as any change in personnel, addition of new strains of animals, increase in animal numbers, breeding, etc. Amendments involving personnel are reviewed and approved by the IACUC chair or designee. All other amendments are reviewed and approved by the full IACUC, which may request further information before granting approval. Additional approval may be required from the animal facility and/or safety office.*

Significant Changes: *The following is the list of significant changes that **will require** submission of a new protocol: (1) Changes in the objectives of a study, (2) Switching from non-survival surgery to survival surgery, (3) Adding a new USDA species.*

*The following is the list of changes that **may** require submission of a new protocol: (1) Changes in the number of animals to be used, (2) Changes in anesthetic agent(s), the use or withholding of analgesics, and methods of euthanasia, (3) Changes in the duration, frequency, or number of procedures performed on an animal, (4) Change in Principal Investigator, (5) Increase in pain category, (6) Increase in invasiveness of a procedure or discomfort to an animal, (7) Change in species.*

The Committee has unanimously voted in favor for the following process for Veterinary Verification and Consultation (VVC) Amendments:

Veterinary Verification and Consultation (VVC)

Veterinary Verification and Consultation (VVC) is a method for approving significant changes to an approved protocol as they relate to anesthesia, analgesia or rodent euthanasia. This is not considered a Designated Member Review but rather the Attending Veterinarian's verification that the changes requested are in compliance with the IACUC Policy, *Euthanasia of Mice, Rats or Guinea pigs* or the IACUC approved formulary. Changes that may be reviewed by VVC are: (a) change in the use or addition of an anesthetic or analgesic. These changes are based on the IACUC approved formulary. The types of changes that can be proposed include: the type of anesthetic or analgesic, the method of administration, the duration of administration or dosage changes; (b) change in or addition of a method of rodent euthanasia. This change/addition is based on the existing IACUC approved policy *Euthanasia of Mice, Rats or Guinea Pigs*. The timeframe for VVC review and response to the amendment upon receipt from the IACUC Manager is 48 hours.