

Annual Report to OLAW

Institution: North Carolina State University
Assurance Number: D16-00214
Reporting Period: January 1 – September 30 2020

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: May 21 2020	Date 2:
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B. Facility Inspections

Multiple sites and dates – see table below:

COS: College of Sciences

CVM: College of Veterinary Medicine

CALS: College of Agriculture and Life Sciences

We were granted a facility inspection waiver from OLAW on April 1, 2020 for the requirement of the IACUC to inspect, at least once every six months, of all NC State University's (A3331-01) animal facilities (including satellite facilities) using the Guide as a basis of evaluation.

Laboratory, Unit or Building	First Inspection Date	Second Inspection Date
COS site 1	January 08 2020	August 5 2020
COS site 1	January 08 2020	July 30 2020, Aug 3 and 5 2020
COS site 1	January 08 2020	July 28 and 29 2020
COS site 1	January 08 2020	July 27 2020, August 11, 2020
COS site 2	January 09 2020	August 19 2020
COS site 3	March 4 2020	September 22, 2020
COS site 4		August 5, 11 2020
COS site 4		July 29, 2020
CVM site 1	March 06 2020	September 10 2020
CVM site 1	March 6 2020	September 10, 11 2020
CVM site 1		1. July 15, 2020 2. August 12, 2020 3. July 29, 2020
CVM site 2	April 22, 2020	
CVM site 3	June 15, 2020	
CVM site 4		July 24, 28, 29, 31, August 4, 6 2020
CVM site 5		August 4 2020
CVM site 6	March 04, 2020	September 22, 2020

CALS site 1	January 22 2020	August 18 2020
CALS site 2	January 09 2020	August 19 2020
CALS site 3		September 08, 2020
CALS site 9	March 04, 2020	September 16, 2020
CALS site 10	March 04, 2020	September 22, 2020
CALS Site 11	July 10, 2020	
CALS Site 11	Aug 4, 2020	
CALS Site 11	February 07, 2020	August 31, 2020
CALS Site 13	June 17, 2020	

III. Minority Views *[Select A or B]*

- ☒ 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: William Flowers	Name: Richard Best
Signature:  (b) (6) <small>Digitally signed by W.L. Flowers DN: cn=W.L. Flowers, o=North Carolina State University, ou=Department of Animal Science, email=flowers@ncsu.edu, c=US Date: 2020.11.18 10:13:44 -0500</small>	Signature:  (b) (6)
Date: 11/18/2020	Date: 11/30/20

V. Change in Institutional Official N/A

VI. Change in IACUC Membership N/A

Attachments: I. Program Changes

Question D1: Review at least once every six months the Institution's program for humane care and use of animals, using the "Guide" as a basis for evaluation. The IACUC procedures for conducting semiannual program reviews are as follows:

[We no longer send the checklist out for three consecutive meetings.]

Utilizing OLAW's sample Semiannual Program Review Checklist (which includes sections for Occupational Health and Safety, Training of IACUC, PIs and Personnel, PHS Policy/Animal Welfare Assurance, The Guide and Veterinary Care Program), the IACUC Chair includes the checklist on the agenda for a convened quorum meeting. Members present at the meeting review and discuss items on the checklist, evaluating the current program for animal care. The checklist is distributed to all voting members of the IACUC prior to the convened meeting to allow any members unable to attend the meetings to submit questions, suggestions or minority reviews. The program review report to the Institutional Official is finalized during discussion at the following meeting.

Question D6: In accord with the PHS Policy IV.C.1-3, the IACUC shall review and approve, require modifications in (to secure approval), or withhold approval of PHS-supported activities related to the care and use of animals.

[The following changes were implemented to our pre-review and DMR protocol review process:]

Administrative Review:

- New protocol submissions and amendment requests for approved protocols are submitted to the IACUC office by the Principal Investigator. Significant Protocol amendment requests are processed and reviewed the same as new protocols
- Training/ OHS Review: A member of the IACUC Office team checks the names of the individuals named in the application against the list of names of individuals who have completed the required animal care and use training. The date of completion of animal care training must be within three years of the date of receipt of the submission. The names of individuals listed on the protocol must also be checked against the names of faculty, students and personnel who are in compliance with enrollment in the Occupational Health and Safety program. If listed individuals are not in compliance with the training and/or Occupational Health and Safety program requirements, the IACUC Office sends a notification to the applicant (Principal Investigator - PI) regarding the requirements, informing them that IACUC approval will be withheld until the requirements are met. Notices on how to meet the requirements are sent to applicable personnel.
- The IACUC Office conducts an administrative review of the application or amendment to pick up gross omissions before the submission continues within the pre-review process. In cases where need for significant revision is apparent, the IACUC Office may recommend that the PI seek immediate assistance from a Committee member in revising the application or amendment.
- The IACUC Office indicates whether or not a protocol submission would be subject to USDA reporting, using the definition of "animal" included in [9 CFR 1.1](#). The designation is subject to change during the review process. This designation is not final until the protocol is approved. This designation is noted in the master record of the protocol in the RED system.

Pre-Review: Vet Review/ IACUC Member Pre-review

To facilitate the PI's submission of the protocol or amendment, the IACUC Office first assigns a veterinary and IACUC member pre-reviewer to perform an additional level of pre-review prior to distribution to the larger committee by designated member review or Full committee review. The veterinary reviewer will conduct their review with regard to veterinary issues. The veterinarian will usually be a current IACUC member; however, other veterinary reviewers may be utilized as consultants. The IACUC member who conducts the pre-review will also serve as the designated reviewer to provide final approval if full committee review is not requested. Initial contact with the PI for any review should occur within 5 working days of receipt of the review assignment.

Designated Member Review

The NC State IACUC conducts committee reviews of all non-Category E protocols under the Designated Member Review process

Non-Category E protocols:

- If the pre-reviewers are satisfied that the application requires no further revision, they will recommend that the protocol or amendment be sent to all other members of the committee for Designated Member Review notification
- Members are notified by email that they have three (3) working days to review the submission and any member of the IACUC may request full committee review of those research projects.
- If full committee review is not requested, at least one member of the IACUC, designated by the Chairperson and qualified to conduct the review, shall review those research projects and have the authority to approve, require modifications in (to secure approval) or request full committee review of those research projects.
- At any time during the Designated Member Review period, committee members may forward comments with requests for minor revisions (i.e. revisions that would not require discussion at a convened quorum). Any modifications required for approval are sent to the PI or their designee to address and return to the IACUC members for final review and approval by the designated member.
- EXPEDITED REVIEWS: At times, the IACUC Office, in consultation with the IACUC Chair, will approve investigator requests for expedited review. The procedures are the same as above, with one exception. The committee will be allowed a shorter time to respond during Designated Member

Review (1-4 working days), subject to determination by the Chair (or in their stead, the First or Second Vice Chair) and the IACUC Director (or in their stead, an IACUC Coordinator).

- If Full Committee Review (discussion at a meeting) is requested during any part of the review process by the reviewers, the IACUC office is notified of the concerns raised, the PI is notified and the item is placed on the agenda for discussion at the next meeting.

G. The training or instruction available to scientists, animal technicians, and other personnel involved in animal care, treatment, or use is as follows:

[Training course is provided solely through AALAS learning library for all listed on a protocol]

All personnel must successfully complete animal welfare regulatory compliance training (Animal Subjects Tutorial) available through NCSU's account with the AALAS Learning Library before a new protocol submission can be approved.

All principal investigators are required to comply with this training requirement, regardless of their direct or indirect involvement with the animal use described in their applications for vertebrate animal use. PIs must complete the tutorial at least every three years.

All NC State personnel who work unsupervised with experimental animals must also complete the tutorial prior to performing animal manipulations and at least every three years thereafter. This includes Faculty, Postdoctoral associates, Graduate students, NC State staff (e.g., animal care and husbandry technicians) and Undergraduate students who work with animals.

The Animal Subjects Tutorial training course includes descriptions of PHS Policy, Animal Welfare Act regulations, general IACUC principles, and the concepts of Russell and Burch regarding replacement, reduction and refinement of animal use to minimize animal pain and distress in research and teaching.

All personnel identified on an application for vertebrate animal use must comply with this regulatory compliance training requirement or protocol approval will be withheld.