



OFFICE OF RESEARCH AFFAIRS
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June 27, 2019

Re: Assurance D16-00020(A3033-01)

Doreen H. Bartlett
Senior Assurance Officer
Division of Assurances
Office of Laboratory Animal Welfare
National Institutes of Health
6700B Rockledge Drive, Suite 2500, MSC 6910
Bethesda, MD 20892-6910

Dear Ms. Bartlett,

On behalf of the University of California San Diego (UCSD), I would like to thank you and your team for your considerable efforts extended during the OLAW Division of Assurances site visit on March 5 - 7, 2019, of the UCSD animal care and use program. I also want to thank you for your follow-up correspondence dated March 20, 2019, in which you acknowledge a list of commendations identified during your site visit.

Your March 20, 2019, letter also included a list of ten items where there were opportunities for improvement and a request to provide by June 30, 2019, an updated status of eight items. Please see below for a status update on each of the requested items (these are numbered consistently with your March 20, 2019, correspondence):

1. While it is understood that the use of environmental enrichment is currently undergoing review, the application of environmental enrichment was found to be inconsistent for the rodent colonies and lacking in some areas of the zebrafish facilities. The minimum of nestlets for singly housed animals was not consistent between several facilities and there is no current minimum requirement for breeding animals in the environmental enrichment SOP. The use of artificial plants was only found in a couple of zebrafish tanks. It is recommended that the environmental enrichment be reassessed relative to:
 - species specific behavior along with subsequent development or modification of the existing IACUC policy and SOP;
 - inclusion in the protocol approval process the use of scientifically justified departures for the withholding of environmental enrichment;
 - consideration of the appropriate nesting material for nude mice; and
 - consideration of the addition of environmental enrichment for zebrafish held at low densities.

Current Status: The IACUC has performed an extensive and formal review of the literature regarding environmental enrichment for mice and rats. The IACUC has subsequently been vigorously debating the issues as they relate to animals housed at UCSD. At the May 2019 IACUC meeting, a subject matter expert presented on the current science applied to animal housing and its effects on animal health and well being. Following these actions, the IACUC voted to direct the Animal Care Program (ACP) and an established subcommittee to develop a specific proposal to incorporate nesting material as standard housing material for all mice, including nude mice. The UCSD housing and environmental enrichment

IACUC policy 12.03 will be updated once the proposal has been accepted. This is expected to be completed by the fall of 2019. Any deviation from standard requirements will continue to require scientific justification in an approved IACUC protocol.

Subsequent to the OLAW Site visit, all singly housed rats were provided with additional environmental enrichment of plastic tubing unless there is a scientifically justified exception written into the approved IACUC protocol to withhold these tubes. Plastic tubes are one of the enrichment options approved in the current UCSD housing and environmental enrichment IACUC policy 12.03 for singly housed rats. However, the IACUC is currently considering whether or not to make the provision of plastic tubing a standard housing requirement for all rats.

No changes in minimum tank environment have been made for zebrafish at this time. Minimum tank environments are currently dictated for all fish in the UCSD housing and environmental enrichment IACUC policy 12.03. However, minimum tank environments for zebrafish are not listed separately, including zebrafish held at low densities. The UCSD housing and environmental enrichment IACUC policy 12.03 may be revised with regard to zebrafish housing based on the current debate.

2. The use of post-operative analgesics was inconsistently documented in several areas. Ensure documentation clearly indicates the administration of analgesics as specified in the respective protocol.

Current Status: The IACUC has initiated an educational campaign to ensure documentation clearly indicates the administration of analgesics as specified in the respective protocols. Actions taken include:

- Updating a standard form available for use by UCSD investigators
- Distributing this standard form during internal inspections
- Discussing this issue during routine and compliance inspections
- Inclusion in informational campaign distributed to UCSD research investigators and staff

3. Review the weight of rats in (b) (4) in relation to the housing recommendations in the Guide for the Care and Use of Laboratory Animals, 8th edition (Guide).

Current Status: Rat housing was evaluated and found to meet the cage size standards within the "Guide." Animals were able to make normal postural adjustments. No changes have been implemented at this time other than the addition of plastic tubes to cages except where protocol stated requirements allow for an exception.

4. Develop and implement how the IACUC provides oversight of field studies.

Current Status: The IACUC members at the March 20, 2019 IACUC meeting, discussed and approved a method of UCSD IACUC oversight of field studies. This oversight includes requests for additional information to be reviewed by the UCSD IACUC annually. The IACUC Office will notify all Principal Investigators with field studies of this change.

5. Provide IACUC members with access to the approved Animal Welfare Assurance.

Current Status: The UCSD PHS Animal Welfare Assurance was made continuously available electronically to all IACUC members. All IACUC members were notified at the March 20, 2019 IACUC meeting that it was readily available for their review.

6. Review the use of an alternate member(s) on semiannual inspections for regulated species when the primary member is available.

Current Status: The UCSD Institutional Official appointed two more voting members to the IACUC. Two IACUC members will participate in all semiannual inspections of regulated species areas. Alternate members will only participate when the primary member is unavailable.

7. Review the use of personnel protective equipment in the Natural Sciences Building dirty cagewash area.

Current Status: The Natural Sciences Building (NSB) vivarium husbandry management is being transitioned to the ACP. Operational procedures, including the use of personnel protective equipment (PPE) in the dirty side of the NSB cage wash area will be consistent with the rest of campus. PPE use in this area was brought into line with standards throughout the rest of campus immediately after the site inspection. The NSB cage wash is slated for removal. Research equipment will then be processed at the Center for Automated Equipment Processing.

8. Review the storage of cleaning implements and supplies in the isolation room and biohazard areas in the Pacific Hall building.

Current Status: The (b) (4) vivarium husbandry management is being transitioned to the ACP. Operational procedures, including the storage of cleaning implements and supplies will be consistent with the rest of campus. The storage of cleaning implements and supplies in the isolation room and biohazard areas in the (b) (4) vivarium was brought into line with standards throughout the rest of campus immediately after the site inspection.

UCSD is committed to the humane care and treatment of animals in research and takes seriously its commitment to compliance with the Public Health Service Policy on Humane Care and Use of Laboratory Animals. If you have any questions or require any additional information, please contact me at (b) (6) or sandrabrown@ucsd.edu.

Sincerely,

(b) (6)

Sandra A. Brown, PhD
Vice Chancellor for Research
IACUC Institutional Official
Assurance number: A3033-1 / D16-00020

cc: Philip Richter, DVM, PhD, Director, Animal Care Program
Michael Gorman, PhD, Chair, UCSD IACUC
Kristen Anderson-Vicino, MS, Director, IACUC Office

(b) (6)



DEPARTMENT OF HEALTH & HUMAN SERVICES

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July 25, 2019

Re: Assurance D16-00020 (A3033-01)

Sandra A. Brown, Ph.D.
Vice Chancellor for Research Affairs
University of California San Diego
9500 Gilman Drive – 0043
La Jolla, CA 92093

Dear Dr. Brown,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your June 27, 2019 letter providing updated information regarding the University of California San Diego's animal care and use program per OLAW's request of March 20, 2019.

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

For the items described below, we request updated information be provided to OLAW with your 2019 Annual Report due to OLAW by January 31, 2020.

- 1) Please provide an update on the minimum tank requirements for Environment Enrichment for zebra fish.
- 2) Please provide more detail regarding the additional information to be reviewed by the UCSD IACUC for the oversight of field studies.

Thank you for your attention to this matter.

Page 2: Sandra A. Brown, Ph.D.

Please don't hesitate to contact me if you have any further questions.

Sincerely,

7/25/2019

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 Chair, University of California San Diego
Attending Veterinarian, University of California San Diego
Patricia Brown, Director, NIH/OLAW
Brent Morse, Director, Division of Compliance Oversight, NIH/OLAW
Eileen Morgan, Director, Division of Assurances, NIH/OLAW

UNIVERSITY OF CALIFORNIA SAN DIEGO

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SANTA BARBARA • SANTA CRUZ

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Sincerely,

(b) (6)

Sandra A. Brown, PhD
Vice Chancellor for Research
IACUC Institutional Official
Assurance number: A3033-1 / D16-00020

cc: Philip Richter, DVM, PhD, Director, Animal Care Program
Michael Gorman, PhD, Chair, UCSD IACUC
Kristen Anderson-Vicino, MS, Director, IACUC Office

(b) (6)



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March 20, 2019

Re: Assurance D16-00020 (A3033-01)

Sandra Brown, Ph.D.
Vice Chancellor for Research Affairs
University of California San Diego
9500 Gilman Drive – 0043
La Jolla, CA 92093

Dear Dr. Brown,

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 March 5 through March 7, 2019 site visit of the University of California San Diego's (UCSD) 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 spent and information provided by Dr. Richter, the veterinary staff, animal welfare specialists, and all others we had the pleasure of meeting during the three-day site visit. We thank these individuals for escorting us throughout the day, as well as Drs. Richter and (b) (6) assistance in coordinating the logistical arrangements, and Ms. Anderson-Vicino for providing all requested documents.

We noted particular program elements that were commendable including:

- Good overall health of animals along with appropriate use of health observation card flags;
- Performance based cage change approach in many of the facilities based on sound performance standards;
- CO₂ euthanasia systems with appropriate equipment and instructions posted that were compliant with the AVMA Guidelines;
- Excellent Animal Operations Center (AOC) for centralized oversight and coordination of all animal facility environmental monitoring, animal care issues, troubleshooting, and tracking of personnel status;
- Excellent Centralized for Automated Equipment Processing (CAEP) area that also provided a work environment free of dust, high temperatures, and humidity frequently seen in cagewash areas;
- Veterinarians and IACUC Chair who are very involved in the animal care and use program;
- Excellent and dedicated staff and facility management personnel who perform with outstanding attention to detail;
- Exceptional and consistent knowledge demonstrated by all staff regarding policies and other programmatic elements.

- Comprehensive protocol form developed by the IACUC that effectively utilizes expandable sections to reduce the burden to the Principal Investigator while still capturing significant items where needed. Of special note is the personnel qualifications form linked to training needs;
- Well-developed and comprehensive website for research staff working with animals that includes how to report animal welfare concerns, “Top 10 Things You Should Know”, and a letter to new investigators;
- Good oversight of the occupational health and safety program with multilevel training based on risk assessment of personnel; online reporting for injury reports integrated with Environmental Health and Safety (EHS) training; inclusion of typical topics such as blood borne pathogens but also ladder safety and ergonomic training with the encouragement of the incorporation of daily ergonomic exercises by the staff;
- Sophisticated database for the ongoing integration of training records for EHS, Animal Care Program (ACP), and researcher training;
- Online orientation course regarding animal research, including training on the emotional and psychological effects of euthanasia as well as the provision of written narration for individuals with English as a second language;
- Well-tuned emergency and disaster plan utilizing the AOC to maximize communication efficiency and responsiveness;
- Comprehensive “Red Book” with action plans regarding the handling of potential disasters for all research facilities;
- Excellent level of sanitation of the physical plant and equipment; and
- Excellent security and access control systems for the animal facilities.

Some areas which would benefit from additional improvements as follows:

1. While it is understood that the use of environmental enrichment is currently undergoing review, the application of environmental enrichment was found to be inconsistent for the rodent colonies and lacking in some areas of the zebrafish facilities. The minimum of nestlets for singly housed animals was not consistent between several facilities and there is no current minimum requirement for breeding animals in the environmental enrichment SOP. The use of artificial plants was only found in a couple of zebrafish tanks. It is recommended that the environmental enrichment be reassessed relative to:
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3. Review the weight of rats in (b) (4) in relation to the housing recommendations in the *Guide for the Care and Use of Laboratory Animals*, 8th edition.
4. Develop and implement how the IACUC provides oversight of field studies.
5. Provide IACUC members with access to the approved Animal Welfare Assurance.
6. Review the use of an alternate member(s) on semiannual inspections for regulated species when the primary member is available.
7. Review the use of personnel protective equipment in the Natural Sciences Building dirty cagewash area.
8. Review the storage of cleaning implements and supplies in the isolation room and biohazard areas in the (b) (4) building.
9. Include as a program change a description of the use of veterinary verification and consultation (VVC) for protocol review in your institution’s 2019 Annual Report to OLAW.


10. Identify the roles to which alternate members are assigned in your institution's 2019 Annual Report to OLAW (e.g. Alternate Member, Alternate Veterinarian).

Please provide OLAW with an updated status of the items #1 through #8 listed above by June 30, 2019.

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

Sincerely,

3/20/2019

 Doreen H. Bartlett

Signed by: Doreen H. Bartlett -S

Doreen H. Bartlett
Senior Assurance Officer
Division of Assurances
Office of Laboratory Animal Welfare, NIH

cc: IACUC Chair, University of California San Diego
Attending Veterinarian, University of California San Diego
Patricia Brown, Director, NIH/OLAW
Brent Morse, Director, Division of Compliance Oversight, NIH/OLAW
Eileen Morgan, Director, Division of Assurances, NIH/OLAW



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Facsimile: (301) 402-7065

February 19, 2019

Re: Assurance D16-00020 (#A3033-01)

Sandra A. Brown, Ph.D.
Vice Chancellor for Research Affairs
University of California San Diego
9500 Gilman Drive – 0043
La Jolla, CA 92093

Dear Dr. Brown,

On behalf of the Office of Laboratory Animal Welfare (OLAW) I am writing to inform you that we are planning a visit to University of California San Diego on March 5-7, 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. Patricia Brown, DVM, Brent Morse, DVM, Lynn Anderson, DVM, and Shannon Stutler, DVM. 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 (b) (6) and we can discuss the entry requirements and the plan for OLAW's visit.

Sincerely,

2/19/2019

X Doreen H. Bartlett

Signed by: Doreen H. Bartlett -S

Doreen H. Bartlett

Senior Assurance Officer

Division of Assurances

Office of Laboratory Animal Welfare, NIH

cc: IACUC Contact

Director, Animal Care Program, Campus Veterinarian