



DEPARTMENT OF HEALTH and HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:

Office of Laboratory Animal Welfare
Division of Assurances
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FOR EXPRESS MAIL:

Office of Laboratory Animal Welfare
Division of Assurances
6700B Rockledge Drive, Suite 2500
Bethesda, Maryland 20817
Telephone: (301) 496-7163

July 28, 2020

Reference Assurance: #D16-00462 (A3784-01)

Karl V. Steiner, Ph.D.
Vice President of Research
University of Maryland, Baltimore County
1000 Hilltop Circle
Baltimore, Maryland 21250

Dear Dr. Steiner:

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt on July 21, 2020, of the University of Maryland, Baltimore County's recent Semiannual Report to the IO (dated July 16, 2020), updates on SOPs, implementation of the Veterinary Health Check mechanism, and information on recent animal care and use program changes in response to OLAW's request of May 15, 2020.

On behalf of this Office, we thank you for providing the updates on the requested information as outlined in OLAW's letter. Upon review it appears that the UMBC animal care and use program is continuing to "move in a positive direction".

OLAW is requesting continued updates on the status of the item listed:

- Veterinary Program Oversight

OLAW's Response:

For OLAW to have confidence in the animal care and use program at UMBC, please continue to provide periodic updates (every 4 months) on the actions taken by the IACUC and the Institutional Veterinarian, in order to support and enhance the animal care and use program. Provide OLAW with a copy of the Annual Report for the 2020 Reporting Period [partial year, January 1 – September 30, with the Annual Report due to OLAW by December 1, 2020].

Note: Please submit the requested Annual Report to OLAW to my attention.

The following deficiencies were noted on the Semiannual Report to the IO (dated July 16, 2020):

- *"2 cages of pair housed rats third rack in the back second row down need to be separated. The rats are too big to be pair housed. PI was instructed to separate the cages ASAP. Completed on 7/14/20."*

OLAW's Response:

Lack of caging is not an adequate justification for not socially housing animals. There are larger rat cages available that can be obtained for rats whose size exceeds Guide standards for pairing in current caging. Provide OLAW with further information including a plan and schedule for socially housing the rats.

- *"Multiple cages with expired protocol on cage cards- CB010611215 & CB018661518. Cage cards need to be updated with the current protocols – (b) (4)."*

OLAW's Response:

Although the deficiency had a correction date (7-14-2020), what is the procedure and /or training in place to ensure cage card protocol information is current? It appears that this is the responsibility of the PI, because the corrective action indicated that - *"the PI was instructed to replace the cage cards with current protocol #'s"*. Is the husbandry/ technician staff trained to verify cage card protocol dates? Please provide OLAW with an update on the procedures for generating (i.e. labeling with required protocol information), and the post approval monitoring of cage cards.

Note: Self-report all incidents of non-compliance to OLAW as per the *PHS Policy IV.F.3 and the NIH Guide Notice: NOT-OD-05-034*.

Please provide OLAW with the next update of all other incidents and actions no later than November 30, 2020. Thank you for your attention to these matters. We look forward to hearing from you. Please don't hesitate to contact us if you have further questions.

Sincerely,

7/28/2020

X Venita B. Thornton, DVM, MPH

Venita B. Thornton, DVM, MPH

Senior Assurance Officer

Signed by: PIV

Venita B. Thornton, DVM, MPH

Senior Assurance Officer, Division of Assurances

Office of Laboratory Animal Welfare, NIH

Cc:

Charles Bieberich - IACUC Chairperson

(b) (6)

Axel Wolff - Deputy Director, NIH/OLAW

Eileen Morgan- Director, Division of Assurances, NIH/OLAW



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Baltimore, Maryland 21250
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July 21, 2020

Assurance #: D16-00462

Venita B. Thorton, DVM, MPH
Senior Assurance Officer
Division of Assurances
Office of Laboratory Animal Welfare, NIH

Dear Dr, Thorton,

On behalf of the UMBC Institutional Animal Care and Use Committee, attached is information and updates related to the OLAW site visit report as requested in your correspondence of May 15, 2020.

Thank you as always for your suggestions and guidance to improve our animal care program at UMBC. If you need any further details or clarification, please feel free to reach out to Andy Glenn or Tim Sparklin in the Office of Research Protections and Compliance.

With appreciation,

(b) (6)

Karl V. Steiner, PhD
Office of the Vice President for Research
University of Maryland, Baltimore County

cc: Charles Bieberich, PhD, IACUC Chair

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1. Qualifications of Back-up Veterinarian

The (revised) Assurance describes - *“Backup and on-call veterinary care, is delegated to and provided by licensed qualified veterinarians from the University of Maryland, Baltimore, Program of Comparative Medicine, Veterinary Resources. As a result, the UMBC animal care program is supported 24/7 by the UMB Comparative Medicine program.”*

OLAW’s Response:

Provide information to include the Name, Qualifications and Degrees, for one of the veterinarians providing backup, emergency, weekend and/or after hours veterinary clinical care in the absence of the Veterinarian with Program Authority.

Degrees: [Enter professional degrees and enter name of 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.]

Training or experience in laboratory animal medicine or in the use of the species at the institution: [Briefly describe the veterinarian’s training or experience in laboratory animal science and medicine or with the species housed. Do not include or attach a CV].

UMBC response:

The veterinarian providing backup, emergency, weekend and/or after hours veterinary clinical care in the absence of the Veterinarian with Program Authority is:



(b) (6)

3. IACUC oversight

UMBC indicated –*“The IACUC continues to provide program oversight via review and approval of animal protocols. The IACUC continues to create guidance on the program as well as promoting, via the OPRC, and creating educational opportunities for members, caretakers and facility staff. The IACUC will also provide more direction to the animal care program by being directly involved with SOP’s review and approval for the animal facility in addition to ensuring all staff are appropriately trained on SOP’s”.*

OLAW’s Response:

For OLAW to have confidence in the animal care and use program at UMBC, please provide periodic updates (every 4 months) on the actions taken by the IACUC and the Institutional Veterinarian, in order to support and enhance the animal care and use program. Provide OLAW with a copy of the next Semiannual Report to the Institutional Official. OLAW recommends the use of the Semiannual Program Review and Facility Inspection Checklist to ensure program oversight of appropriate topic areas. For guidance on the semiannual program review and facility inspection please refer to the OLAW website at the following [URL:https://olaw.nih.gov/resources/documents/cheklist.htm](https://olaw.nih.gov/resources/documents/cheklist.htm).

Please self-report all incidents of non-compliance to OLAW as per the *PHS Policy IV.F.3 .and the NIH Guide Notice: NOT-OD-05-034*.

Note: Please provide the requested documentation to OLAW to my attention by **September 30, 2020**.

UMBC response:

The UMBC IACUC performed its semiannual inspection on July 10, 2020. A report was presented to the UMBC Institutional Official on July 16, 2020. This report details actions requested by the IACUC with dates for compliance. A copy of the semiannual inspection is attached. UMBC is committed to inform OLAW of all incidents of non-compliance. The next update of incidents and actions will be submitted no later than November 30, 2020.

4. Designated Member Review

The UMBC SOP states – *“3.3. At least one IACUC member along with the attending vet is assigned by the Chairperson (or designee) to conduct the DMR.”*

OLAW’s Response:

The description for DMR requires modification regarding the responsibility of the Chairperson, rather than a designee, when selecting the designated reviewers. The PHS Policy IV.C.2. states - *“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.”*

UMBC response:

The designated member review (DMR) SOP has been updated to remove "Designee" and replaced by "designated by the chairperson" to provide clarification on who is assigned to perform DMR appropriately.

5. Veterinary Check

UMBC describes that they will implement a veterinary check animal health log in the new vivarium, that lists animals that require veterinary medical checks.

OLAW's Response:

Provide OLAW with update upon implementation of the Veterinary Health Check mechanism.

UMBC response:

The "veterinary check animal health log" was created, which will be used by the Vet and caretaking staff upon opening of the new vivarium. The new log includes information such as date of discovery and by whom, room location, protocol number, vet initials and date of the first health check, follow up vet initials and dates. We have also included two comment sections, one for reason for concern and one other section is for vet comments concerning treatment.

6. BSL2 facility SOP

UMBC notes the creation of an SOP to describe the mechanism to document the BSL2 facility procedures, in the new vivarium.

OLAW's Response:

Provide OLAW with update upon implementation of the SOP created for the BSL2 facility procedures in the new vivarium.

UMBC response:

The facility manager continues to work on a final version of the BSL-2 facility SOP. The manager will ensure that facility personnel and principal investigators are informed and are appropriately trained in SOP procedures. The SOP will also be posted in the BSL-2 facility. UMBC notes the vivarium opening has been delayed due to the COVID-19 restrictions. UMBC will provide OLAW with an update upon implementation of the SOP.



To: Karl Steiner
Vice President for Research

From: Institutional Animal Care and Use Committee

Subject: Report of the IACUC's Semiannual Evaluation of Animal Care and Use Program and Inspection of Facilities

Date: July 16th, 2020

This represents the semiannual report of the Institutional Animal Care and Use Committee (IACUC), as required by the PHS Policy on Humane Care and Use of Laboratory and as a condition of the University of Maryland, Baltimore County's (UMBC) Animal Welfare Assurance on file with the Office of Laboratory Animal Welfare (OLAW), and USDA Animal Welfare Regulations, 9 CFR Chapter I, subchapter A, as applicable.

As specified in the PHS Policy at IV.A.2, all of the institution's programs and facilities for activities involving animals have been evaluated by the IACUC and will be reevaluated by the IACUC at least once every six months. Our report to you contains a description of the nature and extent of this institution's adherence to the 8th edition of the *Guide for the Care and Use of Laboratory Animals (2010)*.

Evaluation of the Animal Care and Use Program

The IACUC conducted its semiannual evaluation of UMBC's animal care and use program on **July 10th 2020** using the *Guide for the Care and Use of Laboratory Animals*, and, as applicable, USDA Animal Welfare Regulations, 9 CFR Chapter I, 2.31.

The Committee used the *Guide for the Care and Use of Laboratory Animals* and other pertinent resources, e.g., the PHS Policy, the Code of Federal Regulations (Animal Welfare) as a basis for the review. To facilitate the evaluation, the Committee used a checklist based on the Sample OLAW Program and Facility Review Checklist from the OLAW website. The evaluation included, but was not necessarily be limited to, a review of the following: a) IACUC Membership and Functions; b) IACUC Records and Reporting Requirements; c) Husbandry and Veterinary Care (all aspects); d) Personnel Qualifications (Experience and Training); and d) Occupational Health and Safety. In addition, the evaluation included a review of the Institution's PHS Assurance. No member was involuntarily excluded from participating in any portion of the review.

IACUC Approved Departures from the Guide

There are currently no IACUC approved departures from the Guide.

Program Deficiencies.

No deficiencies were identified in the animal care and use program and all aspects of the program are consistent with the *PHS Policy*, the *Guide*, and applicable Animal Welfare Regulations.

Inspection of Animal Facilities

The IACUC inspected UMBC's animal facilities on **July 10, 2020** using the *Guide*, and, as applicable, USDA Animal Welfare Regulations, 9 CFR Chapter I, 2.31.

Members of the Committee visited all of the UMBC's facilities where animals are housed or used, i.e., holding areas, animal care support areas, storage areas, procedure areas, and laboratories where animal manipulations are performed. Equipment used for transporting of the animals were also inspected. The Committee used the *Guide for the Care and Use of Laboratory Animals* and other pertinent resources, e.g., the PHS Policy, the Code of Federal Regulations (Animal Welfare) as a basis for the inspection. To facilitate the evaluation, the Committee used a checklist based on the Sample OLAW Program and Facility Review Checklist from the OLAW website. No member was involuntarily excluded from participating in any portion of the inspection. A description of our findings for each of the campus' animal facilities is detailed below.

Program Deficiencies.

There are **seven** minor deficiencies that were identified in the animal facilities. All aspects of the animal care in these facilities need to be consistent with the *PHS Policy*, the Guide, and applicable Animal Welfare Regulations.

Minority Views

There are no minority views

SEMIANNUAL PROGRAM REVIEW & FACILITY INSPECTION REPORT PLAN & SCHEDULE FOR CORRECTING DEFICIENCIES

DATE: July 14, 2020

MEMBERS IN ATTENDANCE: Due to Covid-19 and UMBC Social Distancing policy the attending Veterinarian Turhan Coksaygan and the IACUC Chair Charles Bieberich attended the inspection. Also, in attendance was (b) (6) to record the findings.

Deficiency Category *	✓	Location	Deficiency & Plan for Correction	Responsible Party	Correction Schedule & Interim Status	Date Complete
M		(b) (4)	2 cages of pair housed rats third rack in the back second row down need to be separated. The rats are too big to be pair housed.	Dr. Bieberich	PI was instructed to separate the cages ASAP	Completed on 7/14/20
M			Carboy in the room not labeled with liquid inside of it. Carboy needs a label identifying the liquid as well as a label identifying sanitizing date. Carboy needs to be sanitized monthly.	Dr. Bieberich	PI was instructed to create an identification label and to record sanitizing dates	Completed on 7/14/20
M			Multiple cages with expired protocol on cage cards- CB010611215 & CB018661518. Cage cards need to be updated with the current protocols	Dr. Bieberich	PI was instructed to replace the cage cards with current protocol #'s	Completed on 7/14/20
M			Multiple cages with expired protocol on cage cards- CB018661518. Cage cards need to be updated with the current protocols	Dr. Bieberich	PI was instructed to replace the cage cards with current protocol #'s	Completed on 7/14/20
M			Food Containers were not labeled with identification or mill date. Please add a label to identify the food contents contained within.	Dr. Bieberich	PI was instructed to label the food containers	Completed on 7/14/20
M			Multiple cages with expired protocol on cage cards- CB018661518. Cage cards need to be updated with the current protocols	Dr. Bieberich	PI was instructed to replace the cage cards with current protocol #'s	Completed on 7/14/20
M			Restrictor valve needs to be changed in euthanasia chamber to meet current 2020 regulations	Dr Coksaygan	Attending Vet was notified to correct the valve	Completed on 7/17/20

- * A = acceptable
M = minor deficiency
S = significant deficiency (is or may be a threat to animal health or safety)
C = change in program (PHS Policy IV.A.1.a.-i.) (include in semiannual report to IO and in annual report to OLAW)
NA = not applicable
✓ Check if repeat deficiency



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FOR EXPRESS MAIL:

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Telephone: (301) 496-7163

May 15, 2020

Reference Assurance: #D16-00462 (A3784-01)

Karl V. Steiner, Ph.D.
Vice President of Research
University of Maryland, Baltimore County
1000 Hilltop Circle
Baltimore, Maryland 21250

Dear Dr. Steiner:

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt on April 17, 2020, of the University of Maryland, Baltimore County's revised 2019 Annual Report to OLAW, the requested Animal Program SOPs, revised protocol approval documentation, and information on recent animal care and use program changes in response to OLAW's request of December 19, 2019.

On behalf of this Office, we thank you for providing the requested information as outlined in OLAW's letter, which details the changes to your animal care and use program's procedures and facility practices, regarding weekend and holiday facility coverage, departures from the Guide, reporting animal welfare concerns, tracking neonates, tracking animal numbers, and updating SOPs.

Please provide OLAW further information and updates on the status of the items listed:

1. Qualifications of Back-up Veterinarian

The (revised) Assurance describes - *"Backup and on-call veterinary care, is delegated to and provided by licensed qualified veterinarians from the University of Maryland, Baltimore, Program of Comparative Medicine, Veterinary Resources. As a result, the UMBC animal care program is supported 24/7 by the UMB Comparative Medicine program."*

OLAW's Response:

Provide information to include the Name, Qualifications and Degrees, for one of the veterinarians providing backup, emergency, weekend and/or after hours veterinary clinical care in the absence of the Veterinarian with Program Authority.

Degrees: [Enter professional degrees and enter name of 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.]

Training or experience in laboratory animal medicine or in the use of the species at the institution: [Briefly describe the veterinarian's training or experience in laboratory animal science and medicine or with the species housed. Do not include or attach a CV].

2. Veterinary Program Oversight

UMBC indicated - *"... the Attending Veterinarian participates as a member on the UMBC IACUC, provides advice on UMBC's animal program, including policies and procedures, animal welfare and health, caretaker occupational health, and zoonosis control programs."*

- UMBC stated – *"Overall, UMBC's veterinary care meets the primary goal of providing appropriate care as described in the Assurance."*

3. IACUC oversight

UMBC indicated – *"The IACUC continues to provide program oversight via review and approval of animal protocols. The IACUC continues to create guidance on the program as well as promoting, via the OPRC, and creating educational opportunities for members, caretakers and facility staff. The IACUC will also provide more direction to the animal care program by being directly involved with SOP's review and approval for the animal facility in addition to ensuring all staff are appropriately trained on SOP's."*

OLAW's Response:

For OLAW to have confidence in the animal care and use program at UMBC, please provide periodic updates (every 4 months) on the actions taken by the IACUC and the Institutional Veterinarian, in order to support and enhance the animal care and use program. Provide OLAW with a copy of the next *Semiannual Report to the Institutional Official*. OLAW recommends the use of the *Semiannual Program Review and Facility Inspection Checklist* to ensure program oversight of appropriate topic areas. For guidance on the semiannual program review and facility inspection please refer to the OLAW website at the following URL:
<https://olaw.nih.gov/resources/documents/cheklist.htm>.

Please self-report all incidents of non-compliance to OLAW as per the *PHS Policy IV.F.3.* and the *NIH Guide Notice: NOT-OD-05-034*.

Note: Please provide the requested documentation to OLAW to my attention by **September 30, 2020**.

4. Designated Member Review

The UMBC SOP states – *"3.3. At least one IACUC member along with the attending vet is assigned by the Chairperson (or designee) to conduct the DMR."*

OLAW's Response:

The description for DMR requires modification regarding the responsibility of the Chairperson, rather than a designee, when selecting the designated reviewers. The PHS Policy IV.C.2. states - *"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."*

5. Veterinary Check

UMBC describes that they will implement a veterinary check animal health log in the new vivarium, that lists animals that require veterinary medical checks.

OLAW's Response:

Provide OLAW with update upon implementation of the Veterinary Health Check mechanism.

6. BSL2 facility SOP

UMBC notes the creation of an SOP to describe the mechanism to document the BSL2 facility procedures, in the new vivarium.

OLAW's Response:

Provide OLAW with update upon implementation of the SOP created for the BSL2 facility procedures in the new vivarium.

Please provide OLAW with updates or an interim report regarding the items listed above (items #1, 4, 5, and 6) by **July 31, 2020**. We look forward to hearing from you.

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

Sincerely,

5/15/2020

X Venita B. Thornton, DVM, MPH

Venita B. Thornton, DVM, MPH

Senior Assurance Officer

Signed by: PIV

Venita B. Thornton, DVM, MPH

Senior Assurance Officer, Division of Assurances

Office of Laboratory Animal Welfare, NIH

Cc:

Charles Bieberich - IACUC Chairperson

(b) (6)

Axel Wolff - Deputy Director, NIH/OLAW

Eileen Morgan- Director, Division of Assurances, NIH/OLAW



Office of the Vice President for Research
University of Maryland, Baltimore County
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Baltimore, Maryland 21250
phone 410.455.5636
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April 17, 2020

Assurance #: D16-00462

Venita B. Thorton, DVM, MPH
Senior Assurance Officer
Division of Assurances
Office of Laboratory Animal Welfare, NIH

Dear Dr. Thorton,

On behalf of the UMBC Institutional Animal Care and Use Committee, attached are revised responses, originally submitted on December 19, 2019 to the OLAW site visit.

We want to thank you for the opportunity to submit our revisions that will improve our animal care program at UMBC. If you need any further details or clarification, please feel free to reach out so we might provide you further detail.

With appreciation,

(b) (6)

Karl V. Steiner, PhD
Office of the Vice President for Research
University of Maryland, Baltimore County

cc: Charles Bieberich, PhD, IACUC Chair

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OLAW finding:

"The *attending veterinarian* (AV) is responsible for the health and wellbeing of all laboratory animals used at the institution. The institution must provide the AV with sufficient authority, including access to all animals, and resources to manage the program of veterinary care. The AV should oversee other aspects of animal care and use (e.g., husbandry, housing) to ensure that the Program complies with the *Guide*," *Guide* page 14.

The AV should provide support, direction and guidance to the administration and management of the animal program.

The Assurance describes the following - "The Veterinarian" is present at the institution an average of approximately 10 hours per month. In addition, "The Veterinarian" contributes on average approximately 10 hour per month to the program while off-site reviewing protocols and providing consultation on various program related topics. Provides advice on policies and procedures, experimental animal models, animal welfare, occupational health, hazard containment, and zoonosis control programs. Oversees activities of the animal care program supervisor and personnel. Reviews and inspects the housing and care of animals in each facility on a monthly basis and at each scheduled semi-annual inspection." It was not clear that what is described in the Assurance is occurring at the Institution.

UMBC's Response to these two points:

UMBC has a long-standing contract with the UMB Department of Comparative Medicine to make available an Attending Veterinarian (AV) who is responsible for the health and well-being of animals housed in UMBC facilities. Under this contract, the UMBC Institutional Official (IO) provides the AV with sufficient authority, including access to all animals, and resources to manage the program of veterinary care (as stated in the Animal Welfare Assurance # D16-00462).

The Director of Comparative Medicine, Louis J. DeTolla, VMD, has communicated to Karl V. Steiner, PhD, UMBC's Institutional Official of his assignment of Turhan Coksaygan, DVM, as UMBC's Attending veterinarian. As the Attending Veterinarian, Dr. Coksaygan has full authority for program oversight and responsibilities for clinical care. He participates as a member on the UMBC IACUC, provides advice on UMBC's animal program, including policies and procedures, animal welfare and health, caretaker occupational health, and zoonosis control programs. His responsibilities also include the inspection of housing and care of animals in each facility on a monthly basis and at each scheduled semi-annual inspection. The report of veterinary care is presented and documented in the minutes of each IACUC meeting. Overall,

UMBC's veterinary care meets the primary goal of providing appropriate care as described in the Assurance, which includes the approximate hours of support as identified in our assurance.

The Office of Research Protections and Compliance (ORPC) has updated the membership list in UMBC's Animal Welfare Assurance to reflect the university's Attending Veterinarian.

OLAW finding:

"The IACUC... is responsible for assessment and oversight of the institution's Program components and facilities. It should have sufficient authority and resources (e.g., staff, training, computers and related equipment) to fulfill this responsibility. The committee is responsible for oversight and evaluation of the entire Program and its components as described in other sections of the *Guide*. Its oversight functions include review and approval of proposed animal use (protocol review) and of proposed significant changes to animal use; regular inspection of facilities and animal use areas; regular review of the Program; ongoing assessment of animal care and use; and establishment of a mechanism for receipt and review of concerns involving the care and use of animals at the institution," *Guide* pages 14 and 25. The IACUC should increase the level of program oversight and direction regarding the laboratory animal facility administration and management.

UMBC's Response:

The IACUC continues to provide program oversight via review and approval of animal protocols. The IACUC continues to create guidance on the program as well as promoting, via the OPRC, and creating educational opportunities for members, caretakers and facility staff. The IACUC will also provide more direction to the animal care program by being directly involved with SOP's review and approval for the animal facility in addition to ensuring all staff are appropriately trained on SOP's. The IACUC will also include as part of their semiannual inspections review of staff training records. The IACUC will also require that husbandry SOP's be reviewed annually and updated as needed.

Members of the IACUC had significant input in designing the new ILSB vivarium. That input included advice on the facility's organizational structure and the campus-wide implementation of Quali Protocols, the system now used to administer and manage animal use protocols. In addition, improvements have been made in appropriate facility staffing through resources provided by the Dean of the College of Mathematics and Natural Sciences and the Vice President for Research.

IACUC-identified deficiencies in a semi-annual inspection are forwarded to the facility manager for correction. The ORPC inspection report states a time frame for deficiencies to be completed. The ORPC remains in contact with the manager to verify that corrections are satisfactorily completed. The IO and IACUC receive a copy of the updated semi-annual inspection report for additional comment or approval.

OLAW finding:

The animals housed in the Psychology building are not observed on weekends and holidays. In addition, the animal room log sheets are not completed. Animals should be observed daily. "Animals should be cared for by qualified personnel every day, including weekends and holidays, both to safeguard their well-being and to satisfy research requirements," *Guide* page 74.

UMBC's Response:

Weekend and holiday care are being documented in the Psychology facility since the OLAW site visit. The IACUC verified this coverage on the animal room log sheets at the January 2020 semiannual inspection. The Psychology facility has updated the facility's SOPs to describe such coverage.

OLAW finding:

Re-evaluate departures from the *Guide*. The Assurance describes that there are no departures from the *Guide*. The IACUC meeting minutes documented that there were no departures from the *Guide*. However, an IACUC approved protocol for food restriction was identified, which is a departure from the *Guide* requiring scientific justification and review approval by the IACUC.

UMBC's Response:

Following the IACUCs procedures to identify and document departures from the Guide, the issue identified in the OLAW site visit for protocol Individual Differences in the Response to Exposure to Heavy Particles (Kuali # 6) was reviewed and discussed at a April 2020 IACUC meeting. The investigator provided scientific justification documentation for these departures. The committee discussed the justification, acknowledged this was a departure from the Guide and approved its use. The IACUCs determination were captured in the Kuali protocol review system; correspondence was generated and forwarded to

the investigator. All discussions and recommendations were documented by the ORPC in the meeting minutes. Additionally, this departure will be included in the updated semi-annual report to the IO (January 2020) and will re-evaluated at future semi-annual reviews..

OLAW finding:

Regarding protocol review by the Full Committee when the outcome is "requires modifications to secure approval," it was not clear that the process conducted is consistent with the *PHS Policy*. Please re-evaluate the procedures used when the IACUC reviews the revised protocol to be consistent with the *PHS Policy*

UMBC's Response:

The ORPC created and implemented an SOP that describes when a protocol needs to go to Designated Member Review (DMR) after Full Committee Review (FCR). This SOP is used during the review of new protocol submissions. This SOP is attached.

OLAW finding:

The outcomes and votes of two protocols are not documented in January and October 2019 minutes, the *PHS Policy IV.E.1.b* requires documentation of committee deliberations.

UMBC's Response:

The ORPC captures all committee deliberations within KUALI Protocols. Reducing administrative burden to allow for increased administrative oversight was one of the main goals of the implementation of Kuali.

OLAW finding:

No signage for reporting animal welfare concerns was identified in facilities. Develop a system for reporting animal welfare concerns. The Assurance describes the following - "Notices are located in the animal facilities advising individuals how and where to report animal welfare concerns and stating that any individual who, in good faith, reports an animal welfare concern will be protected against reprisals". "Mechanisms for reporting concerns should be posted in prominent locations in the facility and on applicable institutional websites with instructions on how to report the concern and to whom ... the process should include a mechanism for anonymity, compliance with whistle blower policies ... protection from reprisals, "Guide page 23-24;

UMBC's Response:

Signage was created by the ORPC to describe the university's process for reporting animal concerns and was distributed to animal facility staff, users, and the ILSB manager. These signs have been posted and are in use and have been confirmed during the January 2020 annual inspection.

OLAW finding:

It was not evident that accounting for rodent pups is consistent with OLAW guidance. Animals should be accounted for on some protocol 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 from approved animal numbers for each IACUC protocol.

UMBC's Response:

Facility caretakers have created a procedure to count pups at birth; investigators will document these numbers on the annual usage reporting form as usable and unusable. Protocol animal numbers will be amended on research protocols to reflect increase in total births.

OLAW finding:

It was not clear that animal numbers are being tracked against the approved protocol. Develop centralized animal procurement and a tracking mechanism to ensure incoming animals are accounted for on an approved protocol.

UMBC's Response:

The new procurement system (JAGGEAR-PAWS) will allow for identification of animals purchased for research. The ORPC has recommended that facility caretakers track, on a monthly basis, the number of animals purchased for the facility by downloading data (by category name and category code) from the procurement system. These numbers can be compared and validated with approved animal numbers in approved Kuali protocols.

OLAW finding:

For the new vivarium, develop a comprehensive mechanism for tracking "Vet Health-Check" notices.

UMBC's Response:

UMBC will implement a vet check animal health log that lists animals that are called in for vet checks. The veterinarian will sign off on the sheet upon vet check and will list treatment. This sheet will be kept in animal facility.

OLAW finding:

Develop a mechanism to sanitize automatic watering recoil hoses.

UMBC's Response:

The ORPC has created an SOP to describe how watering recoil hoses will be sanitized. This SOP is attached. Caretaking staff have been informed and trained on the requirements of the SOP.

OLAW finding:

There are no logbooks maintained for monitoring cagewash and autoclave temperatures during operation. Develop a mechanism to document appropriate sanitation.

UMBC's Response:

The ORPC created an SOP describing the mechanism to document temperature validation and in creating logbooks. This SOP is attached. Caretaking staff have been informed and trained on the requirements of the SOP.

OLAW finding:

There is no microbiological monitoring of racks and cages following cage wash. Also, there is no monitoring following room sanitation; Develop mechanism for ensuring effective sanitation. "Whether the sanitation process is automated or manual, regular evaluation of sanitation effectiveness is recommended. This can be performed by evaluating processed materials by microbiologic culture or the use of organic material detection systems (e.g., adenosine triphosphate [ATP] bioluminescence) and/or by confirming the removal of artificial soil applied to equipment surfaces before washing," *Guide* page 73.

UMBC's Response:

The ORPC created SOP's to describe the mechanisms in documenting microbiological monitoring. This SOP is attached. Caretaking staff have been informed and trained on the requirements of the SOP.

OLAW finding:

OLAW encourages development of SOPs for BSL2 procedures prior to opening new facility.

UMBC's Response:

The ORPC created a SOP to describe the mechanism to document BSL2 facility Procedures. This SOP draft is attached and will be finalized before the new vivarium houses animals.

OLAW finding:

While we did not locate an SOP on processes for the care of the zebra fish, the room log had a morning and afternoon log sheet for documenting procedures. For the last few months (July- November 2019) only the afternoon sheet was being completed. This may not be consistent with your own SOPs.

UMBC's Response:

The principal investigator who works with zebra fish has an SOP which states that the fish are required to be fed twice daily and documented. The feedings were carried out but documented incorrectly by the technician. The technician has been retrained to document the feedings twice daily.



LOUIS J. DETOLLA, VMD, MS, PhD, DACLAM
Professor and Director

Comparative Medicine Program

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Karl V. Steiner, PhD
Vice President for Research
University of Maryland, Baltimore County

April 7, 2020

Dear Dr. Steiner,

This is to confirm that I have appointed Dr. Turhan Coksaygan, DVM, PhD, DACLAM, from the Program of Comparative Medicine to serve as the Attending Veterinarian (AV) for UMBC. In this capacity, Dr. Coksaygan will have authority for program oversight and responsibilities for clinical care at UMBC. I request he be provided responsibility, including access to all animals, and resources to manage the program of veterinary care at UMBC, as defined by the Guide for Care and Use of Laboratory Animals.

Dr. Coksaygan has over 15 years' experience in laboratory animal medicine and science, is a faculty professor in our Department of Pathology, and has extensive administrative experience with the IACUC, AAALAC, and USDA policies. His effort devoted to UMBC's animal program remains the same as stated in your Animal Welfare Assurance (D16-00462).

(b) (6)
(b) (6) and may serve as a backup to Dr. Coksaygan in the event he is unavailable. (b) (6)
(b) (6)

In addition, UMBC has full-time access to our veterinary medical staff and if need be, anyone from UMBC may contact me directly to access support of any kind.

Sincerely,

(b) (6)

Louis DeTolla, VMD, MS, PhD, DACLAM
Professor of Pathology, Medicine (Infectious Diseases), and Epidemiology and Public Health
Professor and Founding Director, Program of Comparative Medicine
Member, Marlene and Stewart Greenebaum Comprehensive Cancer Center
Veterinary Medical Officer, and Chief, Veterinary Medical Unit, Baltimore VA Medical Center

Cc: Charles Bieberich, IACUC Chair

(b) (6)
(b) (6)



University of Maryland, Baltimore County

D16-00462

ANIMAL WELFARE ASSURANCE

in accordance with the PHS Policy for

Humane Care and Use of Laboratory Animals

I, Karl V. Steiner, Ph.D., as named Institutional Official for animal care and use at University of Maryland, Baltimore County (UMBC), hereinafter referred to as Institution, by means of this document, provide assurance that this Institution will comply with the Public Health Service Policy on Humane Care and Use of Laboratory Animals, hereinafter referred to as "PHS Policy".

Applicability of Assurance

This Assurance applies whenever this Institution conducts the following activities: all research, research, training, experimentation, biological testing, and related activities involving live vertebrate animals supported by the PHS, HHS, and/or NSF. This Assurance covers only those facilities and components listed below.

A. The following are branches and components over which this Institution has legal authority, included are those that operate under the University of Maryland, Baltimore County. All components that are physically located on the University's Main Campus in Baltimore County, Maryland. There are no off-site satellite facilities and/or other covered components.

B. The following are other institution(s), or branches and components of another institution:

None

Institutional Commitment

- A. UMBC will comply with all applicable provisions of the "Animal Welfare Act" and other Federal statutes and regulations relating to animals.
- B. UMBC is guided by the "U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training."
- C. UMBC acknowledges and accepts responsibility for the care and use of animals involved in activities covered by this Assurance. As partial fulfillment of this responsibility, UMBC will ensure that all individuals involved in the care and use of laboratory animals understand their individual and collective responsibilities for compliance with this Assurance, as well as all other applicable laws and regulations pertaining to animal care and use.
- D. UMBC has established and will maintain a program for activities involving animals in accordance with the Guide for the Care and Use of Laboratory Animals (2010) [the Guide].
- E. UMBC agrees to ensure that all performance sites engaged in activities involving live vertebrate animals under consortium (subaward) or subcontract agreements have an Animal Welfare Assurance and that the activities have Institutional Animal Care and Use Committee (IACUC) approval.

Institutional Program for Animal Care and Use

- A. The lines of authority and responsibility for administering the program and ensuring compliance with this Policy are as follows and as depicted in the attached organizational chart (**Attachment 1**). This shows there are direct and open lines of communication between the IACUC and the Institutional Official (IO) and between the Veterinarian and the IO.
1. The President of the University of Maryland, Baltimore County (UMBC) delegates, through the Provost, to the Vice President for Research to be the Institutional Official (IO) with the authority to sign the UMBC Assurance. The IO is responsible for the overall administration of the Institutional Animal Care and Use Committee (IACUC) at UMBC. The IO ensures that UMBC complies with the "PHS Policy," the Guide, the "Animal Welfare Act," and other Federal statutes and regulations relating to animals. The Vice President for Research appoints members to serve on the UMBC IACUC for a three-year term.
 2. The Chair of the IACUC and the Veterinarian report directly to the IO on all matters relating to animal care and use. The Associate Vice President for Research also reports directly to the IO and serves as a non-voting ex officio member of the IACUC.
 3. The oversight of the Animal Care Facilities is the responsibility of the Veterinarian. The Veterinarian is a voting member of the IACUC and is the designated member who is a Doctor of Veterinary Medicine with experience in laboratory animal science and medicine. The Veterinarian has direct responsibility for activities involving animal care and use at UMBC.
 4. The IACUC oversees the UMBC Animal Care and Use Program, facilities, and procedures. The Chair of the IACUC is selected from the membership of the Committee. The Chair of the IACUC and all of its members are appointed on an annual basis by the IO and report directly to the IO.
 5. The Research Compliance Officer in the Office of Research Protections and Compliance (ORPC) serves as the liaison between faculty members and senior research administrators and provides administrative support for the IACUC, including problem resolution, training, and coordination of IACUC administrative actions and management of the official records of the Committee.
 6. The day to day management of a Departmental Animal Care Facility (Facility) is the responsibility of the Departmental Facility Supervisor (Supervisor). The Supervisor: 1) is a member of the faculty of the department where the facility is housed; 2) establishes Facility procedures in consultation with the Veterinarian and the IACUC that ensures implementation of the policies and procedures of the IACUC, and the directives of the Veterinarian; 3) will make available and post in the Facility a copy of this Assurance; 4) directs the Animal Care Technician(s) and their assistants in the routine care of the animals and the maintenance of the facilities according to established procedures. The Departmental Facilities are also monitored by a faculty chair of the departmental animal care committee.
 7. The routine care of a Departmental Facility is done by the Animal Care Technicians and assistants. The Animal Care Technicians are responsible for implementing the written procedures and policies for animal care set forth by the Supervisor of the Departmental Facility. The Animal Care Technicians will keep written records as required, which are reviewed by the Veterinarian during his/her monthly visits and will immediately inform the Supervisor of any problems with the facility and the care of the animals.

Note: Correspondence [e.g., meeting minutes, recommendations, reports, etc.] from the IACUC to the IO may be routed through administrative channels for informational purposes. However, such correspondence will not be changed, influenced, or delayed in any manner whatsoever.

B. The qualifications, authority, and percent of time contributed by the Veterinarian who will participate in the program is as follows:

Name: Turhan Coksaygan

Qualifications:

DVM, MS, PhD, DACLAM

DVM: University of Ankara, Turkey, MS: Washington State University, PhD: Cornell University, ECFVG Certificate: 2/11/2014, NAVLE: April 2011, State of Maryland License number: 7283

Experience: Dr Coksaygan completed Laboratory Animal Medicine Residency at University of Maryland (UMB) in 2008. He is ACLAM Diplomate since 2011. He is currently Chief of Clinical Veterinary Medicine at UMB. He is responsible for providing and overseeing veterinary medical care to all laboratory animals at UMB, species include non-human primates, dogs, rabbits, sheep, swine, rodents, ferrets, xenopus and fish.

Authority: Dr. Coksaygan has delegated program authority and responsibility for the UMBC's animal care and use program including access to all animals.

Time Contributed to Program: Dr. Coksaygan is present at the Institution an average of approximately 10 hours per month. 100 percent of this time is contributed to the animal care and use program. In addition, Dr. Coksaygan contributes on average approximately 10 hour per month to the program while off-site reviewing protocols and providing consultation on various program related topics.

Backup and on-call veterinary care, off-site protocol review and consultation on various program related topics is delegated to and provided by licensed qualified veterinarians from the University of Maryland, Baltimore, Program of Comparative Medicine, Veterinary Resources.

As a result, the UMBC animal care program is supported 24/7 by the UMB Comparative Medicine program. Both campuses are part of the overall university system of Maryland (USM).

The Veterinarian has responsibility to oversee the program for animal care and use at UMBC and reports directly to the Vice President for Research, who implements the Guide and secures necessary resources and administrative support for the programs at UMBC. Specifically, the Veterinarian:

- Serves on the IACUC and have joint responsibility with the IACUC for animal use and welfare consistent with the *NIH Guide* and USDA "Animal Welfare Act."
- Provides advice on policies and procedures, experimental animal models, animal welfare, occupational health, hazard containment, and zoonosis control programs.
- Oversees activities of the animal care program supervisor and personnel.
- Provides clinical veterinary care and emergency treatment to animals.
- Reviews and inspects the housing and care of animals in each facility on a monthly basis and at each scheduled semi-annual inspection.

C. This institution has established an Institutional Animal Care and Use Committee (IACUC), which is qualified through the experience and expertise of its members to oversee the institution's animal program, facilities, and procedures. The President has delegated to the Institutional Official the authority to appoint the members of the IACUC. In accordance with the Health Research Extension Act of 1985, this delegation of authority is specific and is in writing. The IACUC consists of at least five members, and its membership meets the composition requirements set forth in "PHS Policy" at IV.A.3.b.

Attached is a list of the chairperson and members of the IACUC and their names, degrees, profession, titles or specialties, and institutional affiliations (**See Part VIII.**).

D. The IACUC will:

1. 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: The IACUC will meet at least once every six months to review the Institutional Program for Humane Care and Use of Animals.

The program reviews include, but are not limited to, a review of the following:

- a. IACUC Membership and Functions
- b. IACUC Records and Reporting Requirements
- c. Veterinary Care (Animal Procurement and Transportation, Preventive Medicine, Surgery, Pain and Distress-Anesthesia and Analgesia, Euthanasia, Drug Storage and Control)
- d. Personnel Qualifications and Training
- e. Occupational Health and Safety

In addition, the evaluation will include a review of the Institution's PHS Assurance. If program deficiencies are noted during the review, they will be categorized as significant or minor and the Committee will develop a reasonable and specific plan and schedule for correcting each deficiency. A significant deficiency is one that is or may be a threat to the health and safety of the animals or personnel.

The IACUC will ensure no member desiring to participate in any portion of the program reviews is involuntarily excluded. All meetings will be posted on the UMBC IACUC website by the Office of Research Protections and Compliance (ORPC) and reminder notices will be sent at least two weeks prior to members. UMBC has developed the IACUC Semi-Annual Review Form for use in evaluation of the animal care and use program.

2. Inspect at least once every six months all of the Institution's animal facilities, including satellite facilities, using the Guide as a basis for evaluation. The IACUC procedures for conducting semiannual facility inspections are as follows: At least once every six months at least two (2) members of the IACUC will inspect all of the institute's facilities. The facility inspections include, but are not limited to, inspection of the following:

- a. Animal Housing Areas
- b. Feed and Bedding Storage Areas
- c. Cage Wash Areas
- d. Surgery Areas
- e. Animal Procedure Areas
- f. Other Animal Care and Use (AC&U) Areas and AC&U Support Areas
- g. Any equipment used for transporting of the animals.

If deficiencies are noted during the inspection, they will be categorized as significant or minor and the Committee will develop a reasonable and specific plan and schedule for correcting each deficiency. A significant deficiency is one that is or may be a threat to the health and safety of the animals or personnel

The IACUC will ensure no member desiring to participate in any portion of the facility inspections is involuntarily excluded. All meetings will be posted on the UMBC IACUC website by the Office of Research Protections and Compliance (ORPC) and reminder notices will be sent at least two weeks prior to members. UMBC has developed the IACUC Semi-Annual Review Form using the Guide for use in evaluation the animal care and use facilities.

3. Prepare reports of the IACUC evaluations as set forth in the PHS Policy IV.B.3 and submit the reports to the Institutional Official. The IACUC procedures for developing reports and submitting them to the Institutional Official are as follows:

Individual IACUC members will convey their observations to the IACUC Chairperson, or his or her designee, who, in turn, will draft the reports based on the sample OLAW Semiannual Report to the Institutional Official format from the OLAW website.

At a minimum, the report will:

- a. contain a description of the nature and extent of the institution's adherence to the *Guide* and "PHS Policy: and identify specifically any departures from the provisions of the *Guide* and "PHS Policy," and state the reasons for each departure
- b. distinguish significant deficiencies from minor deficiencies. A significant deficiency is one that, consistent with the "PHS Policy," and, in the judgment of the IACUC is or may be a threat to the health or safety of the animals
- c. note any program or facility deficiencies and specify a reasonable and specific plan and schedule for correcting each deficiency
- d. include any minority views filed by members of the IACUC; if there are no minority opinions the report will so state.
- e. will be signed by a majority of the IACUC members.

Copies of the draft reports will be reviewed, revised as appropriate, and approved by the Committee. Following completion of each evaluation, the completed report will be submitted to the Institutional Official within 30-60 days.

4. Review concerns involving the care and use of animals at the Institution. The IACUC procedures for reviewing concerns are as follows: Any individual may report concerns to the IO, IACUC Chair, Attending Veterinarian, or any member of the IACUC. Notices are located in the animal facilities advising individuals how and where to report animal welfare concerns and stating that any individual who, in good faith, reports an animal welfare concern will be protected against reprisals. All reported concerns will be brought to the attention of the full Committee. If necessary the IACUC Chair will convene a meeting to discuss, investigate, and address any reported concern. Reported concerns and all associated IACUC actions will be recorded in the IACUC meeting minutes. The Committee will report such actions to the IO and, as warranted, to OLAW.

5. Make written recommendations to the Institutional Official regarding any aspect of the Institution's animal program, facilities, or personnel training. The procedures for making recommendations to the Institutional Official are as follows: Recommendations regarding any aspects of the institution's animal program or facilities are discussed and developed by the Committee. The Committee's recommendations are included in the IACUC Meeting minutes or a report of the IACUC's evaluations or a separate letter. Such documents are reviewed and approved by the Committee and then submitted to the IO.

6. 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 IACUC procedures for protocol review are as follows: In general, protocols undergo full committee review (FCR) at the next scheduled IACUC meeting. Prior to the review, each IACUC member will be provided with written descriptions of activities (protocols) that involve the care and use of animals. FCR will only be conducted at a convened meeting with at least a quorum of the voting members present. At the convened meeting, the members discuss each protocol in depth after which a motion is made and a vote taken. Outcomes of the FCR by a majority vote of the quorum present are: approve, require modification to secure approval (defer review), or withhold approval.

However, a designated member review (DMR) may be requested by the principal investigator in the event that an expedited review is desired before the next scheduled IACUC meeting. In such instances the protocol will be distributed to all IACUC members to allow all members the opportunity to call for FCR; records of polling of members to obtain concurrence to use the DMR method, or concurrence by silent assent after seven (7) working days, and approval of protocols via DMR are maintained and recorded in the minutes of the next convened IACUC meeting. At least one member of the IACUC, who is qualified to conduct the review, is designated by the chairperson to lead the DMR.

A protocol may be assigned by the IACUC Chair, via the ORPC, to more than one designated reviewer; each reviewer is qualified to conduct this review. Prior to the review, DMRs are provided with written descriptions of activities (protocols) that involve the care and use of animals. They must all review identical versions of the protocol and, if modifications are requested by any one of the reviewers, the other reviewers must be aware of and agree to the modifications. After all required modifications are made, a final revised protocol is submitted to all designated reviewers for review and approval. The DMRs decisions must be unanimous; if not, the protocol will be referred for FCR. Approval of these research projects may be granted only after review at a convened meeting of a quorum of the IACUC and with the approval vote of a majority of the quorum present. Outcomes of the DMR are: approve, require modification to secure approval (defer review), or refer to full committee review. Outcomes of FCR or DMR, including comments, revisions and suggestions are summarized and reported to the principal investigator for response.

In order to approve proposed protocols or proposed significant changes in ongoing protocols, FCR or DMR will conduct a review of those components related to the care and use of animals and determine that the proposed protocols are in accordance with the PHS Policy. In making this determination, the IACUC will confirm that the protocol will be conducted in accordance with the Animal Welfare Act insofar as it applies to the activity, and that the protocol is consistent with the Guide unless acceptable justification for a departure is presented. In either case, the IACUC shall determine that the protocol conforms to the institution's PHS Assurance and meets the following requirements:

- a. Procedures with animals will avoid or minimize discomfort, distress, and pain to the animals, consistent with sound research design.
- b. Procedures that may cause more than momentary or slight pain or distress to the animals will be performed with appropriate sedation, analgesia, or anesthesia, unless the procedure is justified for scientific reasons in writing by the investigator.
- c. Animals that would otherwise experience severe or chronic pain or distress that cannot be relieved will be painlessly killed at the end of the procedure or, if appropriate, during the procedure.
- d. The living conditions of animals will be appropriate for their species and contribute to their health and comfort. The housing, feeding, and nonmedical care of the animals will be directed by a veterinarian or other scientist trained and experienced in the proper care, handling, and use of the species being maintained or studied.

- e. Medical care for animals will be available and provided as necessary by a qualified veterinarian.
- f. Personnel conducting procedures on the species being maintained or studied will be appropriately qualified and trained in those procedures.
- g. Methods of euthanasia used will be consistent with the current recommendations of the American Veterinary Medical Association (AVMA) Guidelines on Euthanasia, unless a deviation is justified for scientific reasons in writing by the investigator.

Required modifications. When the IACUC requires modifications (to secure approval), of a protocol, such modifications are reviewed as follows:

- 1. FCR or DMR following the procedures delineated above.
- 2. DMR if approved unanimously by all members at the meeting at which the required modifications are developed delineated AND if the entire current Committee has previously approved and documented a policy of DMR for required modifications, provided however, that if any member calls for FCR of the modifications, such modifications can only be reviewed and approved by FCR.
- 3. Minor modifications of an administrative nature, i.e., typographical or grammatical errors, required signatures, etc. may be confirmed by IACUC administrative/support personnel.

No member may participate in the IACUC or DMR review or approval of a protocol in which the member has a conflicting interest (e.g., is personally involved in the project) except to provide information requested by the IACUC; nor may a member who has a conflicting interest contribute to the constitution of a quorum. In the event of a conflict of interest, an IACUC member must be excused during the final deliberations and vote of the given protocol. The IACUC may invite consultants to assist in reviewing complex issues. Consultants may not approve or withhold approval of an activity or vote with the IACUC unless they are also members of the IACUC.

Note: Any use of telecommunications will be in accordance with NIH Notice NOT-OD-06-052 of March 24th, 2006, entitled Guidance on Use of Telecommunications for IACUC Meetings under the PHS Policy on Humane Care and Use of Laboratory Animals.

7. Review and approve, require modifications in (to secure approval), or withhold approval of proposed significant changes regarding the use of animals in ongoing activities as set forth in the PHS Policy IV.C. The IACUC procedures for reviewing proposed significant changes in ongoing research projects are the same procedures used to review new protocols as described above in section III.D.6

Examples of changes considered to be significant include changes:

- a. from nonsurvival to survival surgery;
- b. resulting in greater pain, distress, or degree of invasiveness;
- c. in housing and or use of animals in a location that is not part of the animal program overseen by the IACUC;
- d. in species;
- e. in study objectives;
- f. in Principal Investigator (PI); and
- g. that impact personnel safety.

8. Notify investigators and the Institution in writing of its decision to approve or withhold approval of those activities related to the care and use of animals, or of modifications required to secure IACUC approval as set forth in the PHS Policy IV.C.4. The IACUC procedures to notify investigators and the

Institution of its decisions regarding protocol review are as follows: Principal Investigators are notified within 2 weeks of the IACUC decision either by e-mail or letter from the IACUC Chairperson or his/her delegate - generally the Office of Research Protections and Compliance (ORPC).

If the IACUC decides to withhold approval of an activity, it shall include in its written notification to the investigators a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing. The Institutional Official is notified by receiving a copy of the PI's notification letter and/or a copy of the IACUC meeting minutes.

9. Conduct continuing review of each previously approved, ongoing activity covered by PHS Policy at appropriate intervals as determined by the IACUC, including a complete review in accordance with the PHS Policy IV.C.1-4 at least once every three years. The IACUC procedures for conducting continuing reviews are as follows: All ongoing activities are monitored continuously by the Veterinarian and animal care staff and the associated protocols are reviewed by a member or members of the IACUC at least annually. Protocols are approved for a maximum of 36 months. Investigators are required to complete annual updates reporting in accordance with the continuing review dates set by the IACUC. Reporting describes animal use and any changes to all active continuing protocols. Annual reporting on protocol activity are submitted to the ORPC at least 30 days prior to the end date of the initial approval. Upon ORPC review, completed annual review forms may require Designated Review, as described in III.D.6. Designated Member Review is usually conducted by the Chair or his/her designee and the Attending Veterinarian. Annual review reports are made available for IACUC members to review in a secure, file-sharing environment. Annual reviews are assigned by the IACUC Chair, via the ORPC, to a designated reviewer; reviewers are qualified to conduct this review. In such instances the annual review report is distributed to all IACUC members to allow all members the opportunity to call for FCR; records of polling of members to obtain concurrence to use the DMR method, or concurrence by silent assent after seven (7) working days. If a DMR requests a FCR, the ORPC, via the Chair, notifies all IACUC members that the annual review will be a FCR. Approval of annual review reports via DMR are maintained and recorded in the minutes of the next convened IACUC meeting

If activities will continue beyond the expiration date, a new protocol must be submitted, reviewed, and approved [prior to expiration of the original or preceding protocol] as described in Paragraph III.D.6. above. All IACUC members are informed of all annual reporting in the IACUC meeting agenda and discussions are recorded in the IACUC meeting minutes.

A complete de-novo review of continuing protocols is performed at least once every three years; investigators with ongoing studies are notified that their protocols must be resubmitted for a complete review.

Additionally, the Attending Veterinarian conducts monthly, and as necessary, visits to UMBC's animal facilities as a proactive means ensuring that minor issues are identified rapidly for quick correction, and that major issues are prevented. Monthly visit reports are provided to the IACUC.

10. Be authorized to suspend an activity involving animals as set forth in the PHS Policy IV.C.6. The IACUC procedures for suspending an ongoing activity are as follows: The IACUC may suspend an activity that it previously approved if it determines that the activity is not being conducted in accordance with applicable provisions of the Animal Welfare Act, the Guide, the institution's Assurance, or IV.C.1.a.-g. of the PHS Policy. The IACUC may suspend an activity only after review of the matter at a convened meeting of a quorum of the IACUC and with the suspension vote of a majority of the quorum present. If the IACUC suspends an activity involving animals, or any other institutional intervention results in the temporary or permanent suspension of an activity due to noncompliance with the Policy, Animal Welfare Act, the *Guide*, or

the institution's Assurance, the Institutional Official in consultation with the IACUC shall review the reasons for suspension, take appropriate corrective action, and report that action with a full explanation to OLAW.

E. The occupational health and safety program for personnel working in laboratory animal facilities or have frequent contact with animals as follows:

The program is based on risk assessment, education and promotion of safe practices and personnel safety, preventing occupational injury and illness for all personnel involved in the care and/or use of laboratory animals and potentially hazardous agents, and provide guidance on the diagnosis, treatment, and reduction of diseases transmitted from animals to humans (zoonotic diseases). The occupational health and safety program is supported by UMBC Environmental Safety and Health and Office of Research Protections and Compliance and are responsible for implementing and overseeing the program. Supervisors and Principal Investigators are tasked to ensure that their personnel are adequately trained. However, ultimately it is the responsibility of the Institution to ensure that the occupational health and safety program is fully developed, implemented, and maintained.

Every individual (animal care personnel) who will conduct procedures as well as daily care and maintenance involving animals are covered by this program. These include:

- Principal Investigators on IACUC protocols
- Research Staff listed on IACUC protocols
- Animal Care Staff
- Student Employees using and caring for animals

Animal care personnel are enrolled at the time of submission of a new IACUC study, the renewal of an expiring study, or when new personnel are added to a study. Enrollment involves the annual submission of a risk assessment and completion of training as described below.

a. Hazard Identification, Surveillance and Risk Assessment

All animal care employees of the University are required to provide evidence of a physical examination at the time of employment, including history of any allergies, and a current tetanus inoculation with a booster every ten years. Animal care employees may elect to use their personal physician or if it is more feasible use UMBC's medical surveillance provider. In either case, employees must submit the UMBC Laboratory Animal Risk Assessment Form to Environmental Safety and Health. The form assesses if one may be "at risk" by working in the lab animal environment. The form is reviewed by environmental safety and health professionals to determine the individual's potential risks of working in this environment. Personnel are advised that if they are planning to become pregnant, are pregnant, are ill, or have impaired immunocompetence that they should consult by their own physician or UMBC's medical surveillance provider regarding such conditions and how they might pertain to their working with laboratory animals. Evidence of risk assessment is maintained by UMBC Environmental Safety and Health.

UMBC's Policy on Environmental Safety and Health Management and Enforcement provides guidance regarding compliance with federal, state, and local regulations for environmental protection, occupational safety, public health, biological safety, fire safety, hazardous materials management, and UMBC risk management requirements.

Hazards commonly encountered in association with animal research must be identified and described in the IACUC Protocol Application, and typically fall into several broad categories, each with its own requirements for documentation and/or additional review. These categories include:

- Hazardous Chemicals (e.g., carcinogens, toxins)
- Biohazards (e.g., recombinant DNA, viral vectors)
- Radioactive Substances and lasers

When hazards are identified that pose a serious health risk to research personnel and/or vivarium staff, investigators are required to submit for review and approval the appropriate documentation regarding the use of such materials for review and approval, where applicable, to UMBC Environmental Safety and Health or the UMBC Institutional Biosafety Committee.

b. Personnel Training

All animal care employees must register for and complete a required web-based training program at least annually. This program covers the basics of animal safety and working in a laboratory setting as well as specific safety issues zoonoses and allergies and precautions concerning rodents, fish, birds, amphibians, and wild vertebrates. Additional topics covered in the training program include topics related to chemical safety; the proper handling of waste materials; personal hygiene, and other considerations (e.g. precautions to be taken if personnel are pregnant, ill, or have decreased immunocompetence) as appropriate to the risk imposed by their workplace/environment. Evidence of training completion is maintained by UMBC Environmental Safety and Health. UMBC's contract with University of Maryland Family Medicine Associates also offers general in-service program on risk topics including bloodborne pathogens, animal allergens/bites, hazardous materials/chemical exposure radiation exposure) and acute injuries.

c. Personnel Hygiene and Protection

The most common risks present while working in the UMBC animal facilities include:

1. Animal bites and scratches
2. Animal allergens from saliva, urine, blood, dander or fur
3. Zoonotic diseases, i.e. Salmonellosis, Yersinia enterocolitica

The minimum procedures required, as applicable, to minimize those risks include:

1. Training on proper animal handling techniques;
2. Following posted personal protective clothing and equipment requirements;
3. Washing hands after handling animals or related equipment
4. Using disposable supplies whenever possible;
5. Sanitizing lab work areas after animal work.

Eating, drinking and smoking are not allowed in research labs or animal housing areas.

Animal care employees are provided with protective equipment, where appropriate, when working in the animal facilities at UMBC. Protective equipment may include cloth overalls, disposable coveralls, disposable gowns, plastic gowns, rubber gloves, heat insulated gloves, sterile gloves, rubber boots, foot covers, surgical masks,

respirators, face shields, ear protectors, and hats, as appropriate to the circumstance. Closed toed shoes must be worn.

Written guidelines regarding the adherence to established safety and environmental procedures, reporting hazards, potential violations of regulations and health care contact information related to illness and injury are posted in each animal facility.

Any injuries occurring on the job will be reported immediately to the next highest supervisor and UMBC Environmental Safety and Health. When animal care personnel have incurred a work-related injury, the injured person is to be referred directly to: University Health Services, Erickson Hall, Center Road, (b) (6). When University Health Services is not open, employees are referred to: WorkPro Occupational Health, 4807 Benson Avenue, Baltimore, MD 21227, (b) (6)

The housekeeping staff is not routinely allowed access to the animal facilities. In situations where housekeeping, maintenance, or other non-animal care and use personnel must access the animal rooms, they are briefed on appropriate precautions and provided any appropriate PPE and are then are permitted in for a limited amount of time. A member of the animal care staff will be available for escort if needed. If there is extensive or prolonged work to be done the animals are removed prior to the individuals being allowed into the room.\

F. The total gross number of square feet in each animal facility, the species of animals housed therein and the average daily inventory of animals, by species, in each facility is provided in the attached Facility and Species Inventory table (**See Part X**).

G. The training or instruction available to scientists, animal technicians, and other personnel involved in animal care, treatment, or use is as follows: The Office of Research Protections and Compliance coordinates and informs scientists, animal technicians, and other personnel involved in animal care, treatment, or use of training or instructional programs that are available for use. Individuals using animals for the first time or employing unfamiliar techniques are provided on the job training regarding these procedures by the faculty in charge of the animal facility and by the Veterinarian on a regular basis during his/her regular visits.

The training or instruction available to the IACUC, investigators, animal technicians, and other personnel involved in animal care, treatment, or use is as described below:

1. IACUC

Upon appointment, members are provided educational materials including the UMBC Animal Assurance; PHS Policy on Humane Care and Use of Laboratory Animals; the Guide; AVMA Guidelines on Euthanasia, Animal Welfare Act, Regulations and Standards; IACUC Guidebook; and the UMBC IACUC Policy and Procedure Guidebook. They are periodically provided additional information such as reprints of relevant journal articles and guidance updates. Members are provided information about OLAW and Public Responsibility in Medicine and Research meetings and webinars. On the job training also occurs during facility walk through and observation of the protocol review process. UMBC uses the animal welfare training modules available from the Collaborative Institutional Training Initiative (CITI). Supplementary training opportunities are identified and offered to members. A completion certificate is available for printing from the CITI website to each participant and is valid for 3 years. ORPC also tracks the completion of the modules of all participants.

2. Animal Care Personnel, Investigators and Research Technicians

All personnel, including investigators, students, technicians, and facility personnel and caretakers performing procedures using animals must be identified in the Institutional Animal Care and Use Protocol. A description of each individual's qualifications, experience and/or training with the specific animal species, model and procedures must be provided for IACUC review. Any person needing additional protocol-specific training will be identified during the review process and such required training will be a condition of approval of the protocol.

UMBC uses the animal welfare training modules available from the Collaborative Institutional Training Initiative (CITI).

The training includes training or instruction on research or testing methods that minimize the numbers of animals required to obtain valid results and limit animal pain or distress as well as other requirements delineated in 9 CFR, Part 2, Subpart C, Section 2.32(c).

Specifically, training and instruction of personnel must include guidance in at least the following areas:

1. Humane methods of animal maintenance and experimentation, including:
 - a. The basic needs of each species of animal;
 - b. Proper handling and care for the various species of animals used by the facility;
 - c. Proper pre-procedural and post-procedural care of animals; and
 - d. Aseptic surgical methods and procedures;
2. The concept, availability, and use of research or testing methods that limit the use of animals or minimize animal distress;
3. Proper use of anesthetics, analgesics, and tranquilizers for any species of animals used by the facility;
4. Methods whereby deficiencies in animal care and treatment are reported, including deficiencies in animal care and treatment reported by any employee of the facility. No facility employee, Committee member, or laboratory personnel shall be discriminated against or be subject to any reprisal for reporting violations of any regulation or standards under the Act;
5. Utilization of services (e.g., National Agricultural Library, National Library of Medicine) available to provide information:
 - a. On appropriate methods of animal care and use;
 - b. On alternatives to the use of live animals in research;
 - c. That could prevent unintended and unnecessary duplication of research involving animals; and
 - d. Regarding the intent and requirements of the Animal Welfare Act and USDA-APHIS Regulations

On-line training may be used and accepted in lieu in-house training. Any use of on-line training to fulfill training requirements must be approved by the IACUC. Approval and completion of on-line training will be documented.

UMBC uses the animal welfare training modules available from the Collaborative Institutional Training Initiative (CITI). A completion certificate is available for printing from the CITI website to each participant and is valid for 3 years. ORPC also tracks the completion of the modules of all participants.

Specialized Training: Training in experimental methods, i.e., specific animal manipulations and techniques and in the care of new and nontraditional laboratory animal species, will be conducted based on the types of research being conducted and the species being used at the institution.

Additional training materials are available from the University of Maryland, Baltimore, Program of Comparative Medicine, Veterinary Resources are available for animal facility staff and faculty, students, and technicians to use for further training and educational opportunities. ORPC will obtain and make available these materials at any time upon request.

Personnel are also offered the opportunity to attend training courses offered by the University of Maryland, Baltimore, Program of Comparative Medicine, Veterinary Resources.

The Research Compliance Officer in the Office of Research Protections and Compliance (ORPC) will maintain membership in related professional societies and will attend relevant professional conferences in order to ensure regulatory compliance and to provide guidance and training for researchers.

Note: For investigators transferring from other facilities at which they have received similar training, verification of previous training may be accepted in lieu of some Institutional required training. Acceptance of previous training in lieu of the Institution's training is solely at the IACUC's discretion.

Institutional Program Evaluation and Accreditation

All of this Institution's programs and facilities (including satellite facilities) for activities involving animals have been evaluated by the IACUC within the past six months and will be re-evaluated by the IACUC at least once every six months thereafter, in accord with the PHS Policy IV.B.1-2. Reports have been and will continue to be prepared in accord with the PHS Policy IV.B.3. All IACUC semiannual reports will include a description of the nature and extent of this Institution's adherence to the "Guide." Any departures from the "Guide" will be identified specifically and reasons for each departure will be stated. Reports will distinguish significant deficiencies from minor deficiencies. Where program or facility deficiencies are noted, reports will contain a reasonable and specific plan and schedule for correcting each deficiency. Semiannual reports of the IACUC's evaluations will be submitted to the Institutional Official. Semiannual reports of IACUC evaluations will be maintained by this Institution and made available to the OLAW upon request.

This Institution is Category Two (2)—not accredited by the Association for Assessment and Accreditation of Laboratory Animal Care, International (AAALAC). As noted above, reports of the IACUC's semiannual evaluations (program reviews and facility inspections) will be made available upon request. The report of the most recent evaluations (program review and facility inspection) is attached (**Attachment 2**).

Recordkeeping Requirements

This institution will maintain, through ORPC, for at least three years:

1. A copy of this assurance and any modification thereto, as approved by PHS.

2. Minutes of IACUC meetings, including records of attendance, activities of the committee and committee deliberations.
3. Records of applications, proposals, and proposed significant changes in the care and use of animals and whether IACUC approval was given or withheld.
4. Records of any IACUC reports and recommendations (including minority views) as forwarded to the Institutional Official, Karl V. Steiner, Vice President for Research, University of Maryland, Baltimore County.
5. Records of accrediting body determinations.

B. This institution, through ORPC, will maintain records that relate directly to applications, proposals, and proposed changes in ongoing activities reviewed and approved by the IACUC for the duration of the activity and for an additional three years after completion of the activity.

C. All records shall be accessible for inspection and copying by authorized OLAW or other PHS representatives, during University business hours, at reasonable times and in a reasonable manner.

Reporting Requirements

A. UMBC's reporting period is January 1 – December 31. The IACUC, through ORPC and the Institutional Official will submit an annual report to OLAW on January 31 of each year.

The report will include:

1. Any change in the accreditation status of UMBC (e.g., if the UMBC obtains accreditation by AAALAC or AAALAC accreditation is revoked)
2. Any change in the description of UMBC's program for animal care and use as described in this Assurance
3. Any change in the IACUC membership
4. Notification of the dates that the IACUC conducted its semiannual evaluations of UMBC's program and facilities (including satellite facilities) and submitted the evaluations to the Institutional Official, Karl. V. Steiner, PH.D.
5. Any minority views filed by members of the IACUC

B. The IACUC, through ORPC and the Institutional Official, will provide the OLAW promptly with a full explanation of the circumstances and actions taken with respect to:

1. Any serious or continuing noncompliance with the "PHS Policy".
2. Any serious deviations from the provisions of the *Guide*.
3. Any suspension of an activity by the IACUC.

C. Reports filed under VI.A.2. and VI.B above shall include any minority views filed by members of the IACUC.

Institutional Endorsement and PHS Approval

A. Authorized Institutional Official	
Name: Karl V. Steiner, PhD.	
Title: Vice President for Research	
Name of Institution: University of Maryland, Baltimore County	
Address: <i>(street, city, state, country, postal code)</i> 1000 Hilltop Circle, Baltimore, MD 21250	
Phone: (b) (6)	Fax: (b) (6)
E-mail: steinerk@umbc.edu	
Acting officially in an authorized capacity on behalf of this Institution and with an understanding of the Institution's responsibilities under this Assurance, I assure the humane care and use of animals as specified above.	
Signature: (b) (6)	Date: 4/16/2020 7:25:15 PM EDT

B. PHS Approving Official <i>(to be completed by OLAW)</i>	
Name/Title: Office of Laboratory Animal Welfare (OLAW) National Institutes of Health 6705 Rockledge Drive RKL1, Suite 360, MSC 7982 Bethesda, MD USA 20892-7982 (FedEx Zip Code 20817) Phone: +1 (301) 496-7163 Fax: +1 (301) 451-5672	
Signature:	Date:
Assurance Number:	
Effective Date:	Expiration Date:

Membership of the IACUC

Date: April 7, 2020			
Name of Institution: University of Maryland, Baltimore County			
Assurance Number: D16-00462 (A3784-01)			
IACUC Chairperson			
Name*: Charles Bieberich			
Title*: Professor		Degree/Credentials*: Ph.D.	
Address*: (street, city, state, zip code) University of Maryland, Baltimore County, 1000 Hilltop Circle, Baltimore, Maryland 21250			
E-mail*: srosenbe@umbc.edu			
Phone*: 410-455-2237		Fax*: 410-455-3875	
IACUC Roster			
Name of Member/ Code**	Degree/ Credentials	Position Title***	PHS Policy Membership Requirements****
Turhan Coksaygan (V)	DVM.	Veterinarian	Attending Veterinarian
(b) (6)			Scientist
			Scientist
			Scientist
			Non-affiliated member
			Scientist
			Non- Scientist committee member
			Non-voting ex officio member

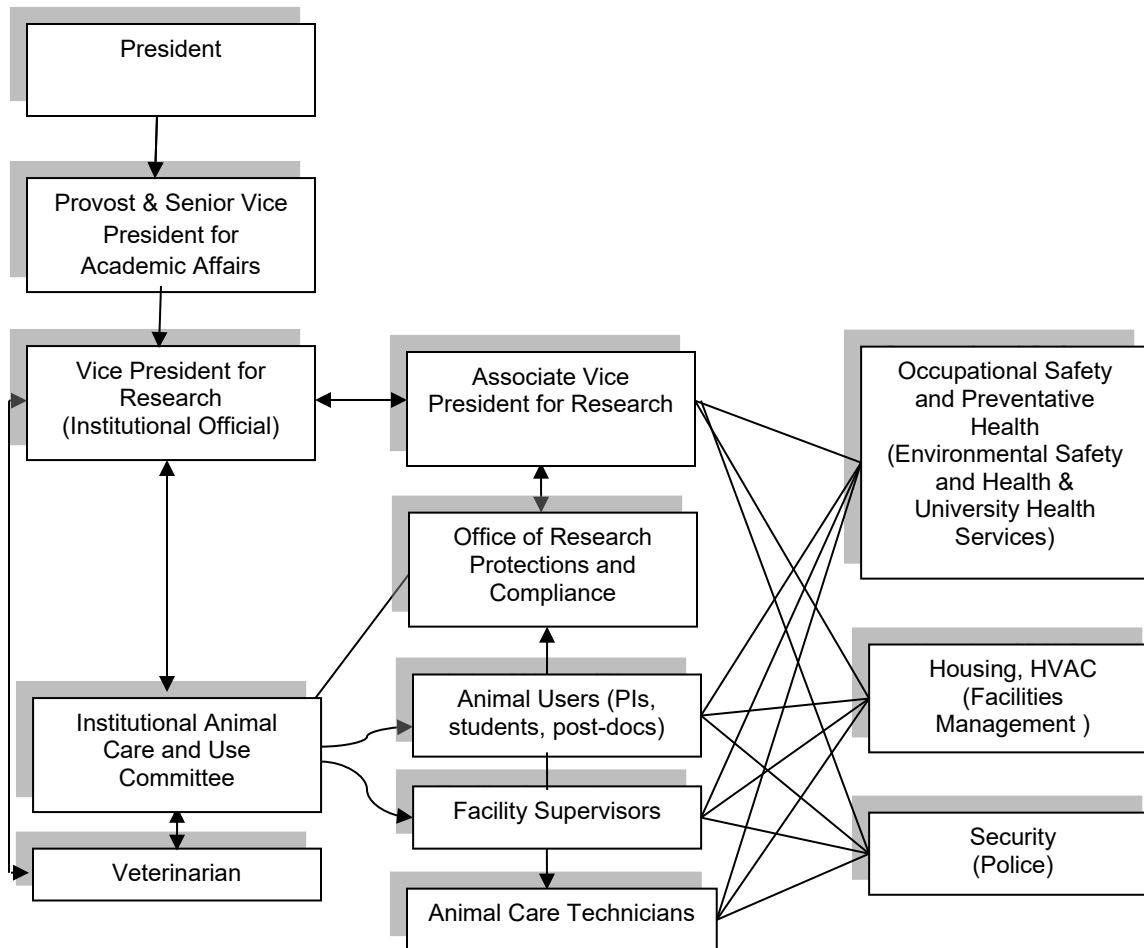
X. Facility and Species Inventory

Date: April 7, 2020			
Name of Institution: University of Maryland, Baltimore County			
Assurance Number: D16-00462 (A3784-01)			
Laboratory, Unit, or Building*	Gross Square Feet [include service areas]	Species Housed [use common names, e.g., mouse, rat, rhesus, baboon, zebrafish, African clawed frog]	Approximate Average Daily Inventory
(b) (4)	183.74	Zebrafish	2,000
	149.56	Mice	475
	150.17	Rats	140
	164.86	Mice	125
	164.86	Mice	560
	164.86	Mice	1050
	164.86	Mice	900
	145.85	Mice	1080
	145.83	Mice	760
	221	Rats	144
	242	Rats	59
	242	Rats	125

*Institutions may identify animal areas (buildings/rooms) by a number or symbol in this submission to OLAW. However, the name and location must be provided to OLAW upon request.

Attachment 1.

Lines of authority and responsibility for the UMBC Animal Care and Use Program



Note: There are open and direct lines of communication between the IACUC and the Institutional Official as well as between the Veterinarian and Institutional Official

Attachment 2.



To: Karl Steiner
Vice President for Research

From: Institutional Animal Care and Use Committee

Subject: Report of the IACUC's Semiannual Evaluation of Animal Care and Use Program and
Inspection of Facilities

Date: January 10, 2020 (updated April 16, 2020)

This represents the semiannual report of the Institutional Animal Care and Use Committee (IACUC), as required by the PHS Policy on Humane Care and Use of Laboratory and as a condition of the University of Maryland, Baltimore County's (UMBC) Animal Welfare Assurance on file with the Office of Laboratory Animal Welfare (OLAW), and USDA Animal Welfare Regulations, 9 CFR Chapter I, subchapter A, as applicable.

As specified in the PHS Policy at IV.A.2, all of the institution's programs and facilities for activities involving animals have been evaluated by the IACUC and will be reevaluated by the IACUC at least once every six months. Our report to you contains a description of the nature and extent of this institution's adherence to the 8th edition of the *Guide for the Care and Use of Laboratory Animals (2010)*.

Evaluation of the Animal Care and Use Program

The IACUC conducted its semiannual evaluation of UMBC's animal care and use program on **January 10, 2020** using the *Guide for the Care and Use of Laboratory Animals*, and, as applicable, USDA Animal Welfare Regulations, 9 CFR Chapter I, 2.31.

The Committee used the *Guide for the Care and Use of Laboratory Animals* and other pertinent resources, e.g., the PHS Policy, the Code of Federal Regulations (Animal Welfare) as a basis for the review. To facilitate the evaluation, the Committee used a checklist based on the Sample OLAW Program and Facility Review Checklist from the OLAW website. The evaluation included, but was not necessarily be limited to, a review of the following: a) IACUC Membership and Functions; b) IACUC Records and Reporting Requirements; c) Husbandry and Veterinary Care (all aspects); d) Personnel Qualifications (Experience and Training); and d) Occupational Health and Safety. In addition, the evaluation included a review of the Institution's PHS Assurance. No member was involuntarily excluded from participating in any portion of the review.

IACUC Approved Departures from the Guide

The IACUC, at its meeting of April 16, 2020, approved a departure from the Guide as identified in Protocol 6. This departure dealt with a food deprivation procedure as described in the behavioral tasks. Animals are monitored closely during these procedures and health concerns reported immediately to the veterinarian. i Members reviewed and approved this departure as documented in the protocol.

Program Deficiencies.

No deficiencies were identified in the animal care and use program and all aspects of the program are consistent with the *PHS Policy*, the *Guide*, and applicable Animal Welfare Regulations.

Inspection of Animal Facilities

The IACUC inspected UMBC's animal facilities on **January 10, 2020** using the *Guide*, and, as applicable, USDA Animal Welfare Regulations, 9 CFR Chapter I, 2.31.

Members of the Committee visited all of the UMBC's facilities where animals are housed or used, i.e., holding areas, animal care support areas, storage areas, procedure areas, and laboratories where animal manipulations are performed. Equipment used for transporting of the animals were also inspected. The Committee used the *Guide for the Care and Use of Laboratory Animals* and other pertinent resources, e.g., the *PHS Policy*, the Code of Federal Regulations (Animal Welfare) as a basis for the inspection. To facilitate the evaluation, the Committee used a checklist based on the Sample OLAW Program and Facility Review Checklist from the OLAW website. No member was involuntarily excluded from participating in any portion of the inspection. A description of our findings for each of the campus' animal facilities is detailed below.

Program Deficiencies.

There are no minor deficiencies that were identified in the animal facilities. All aspects of the animal care in these facilities need to be consistent with the *PHS Policy*, the *Guide*, and applicable Animal Welfare Regulations.

Minority Views

There are no minority views

Updated 4/14/2020

SEMIANNUAL PROGRAM REVIEW & FACILITY INSPECTION REPORT

PLAN & SCHEDULE FOR CORRECTING DEFICIENCIES

DATE: January 10, 2019

MEMBERS IN ATTENDANCE: (b) (6), Charles Bieberich, (b) (6)

Deficiency Category *	✓	Location	Deficiency & Plan for Correction	Responsible Party	Correction Schedule & Interim Status	Date Complete
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- * A = acceptable
- M = minor deficiency
- S = significant deficiency (is or may be a threat to animal health or safety)
- C = change in program (PHS Policy IV.A.1.a.-i.) (include in semiannual report to IO and in annual report to OLAW)
- NA = not applicable
- √ Check if repeat deficiency

Updated 4/14/2020

PROTOCOLS

kuali



Protocol Approval Certification

Protocol 6 Individual Differences in the Response to Exposure to Heavy Particles (PI: Rabin, B M) was Full Board approved on Thursday, April 16th 2020 by the UMBC IACUC . The expiration date is Friday, July 31st 2020.

The Amendment submission * of protocol 6 Individual Differences in the Response to Exposure to Heavy Particles (PI:Rabin, B M) was Full Board approved on Thursday, April 16th 2020 by UMBC IACUC . Please submit a continuing review application on no date provided. The protocol will expire on Friday, July 31st 2020 unless the expiration date is extended in the continuing process.

Please use the protocol number listed above on all correspondence relating to this action, facility cage cards, procurement orders, etc.

Further modifications to approved protocols must be documented through Kuali and appropriately, reviewed, and approved. All amendments are submitted using [Kuali protocols](#). This should be done as soon as the modified procedures are developed and before they are implemented.

Reports of adverse events, which are events that occur consistent with routine care or expected outcomes that results in an unexpected morbidity or mortality in animals that was not

described in the animal use protocol, should be reported at the time of the problem. To report an adverse event using [Kuali protocols](#). In your Manage Protocols screen, look for the clipboard symbol to the right of your protocol. Click on the "Report an Event" button at the top right and describe the event.

It is also your responsibility to provide all information concerning vertebrate animals to any funding agency. If the granting agency requires protocol review, it is also your responsibility to forward a copy of this letter to the Executive Secretary of the assigned Study Section, or to any other appropriate official at the sponsoring agency.

The IACUC approves the use of animals in this research as it meets the standards described in the NIH *Guide for the Care and Use of Laboratory Animals* and the "Animal Welfare Act".

UMBC has an Animal Welfare Assurance on file with the Office of Laboratory Animal Welfare (OLAW). The Assurance Number is **D16-00462**; please use this number when communicating with external sponsors and funding agencies

If you have any questions, please contact the Office of Research Protections and Compliance at compliance@umbc.edu.

*This reflects IACUC approval of the departure from the Guide submitted on April 13 2020.

Reviewed and approved by the UMBC IACUC, 4.16.2020

Procedures to Identify, Evaluate, and Document the Departures from the Guide

When reported by investigators or identified and the Office of Research Protections and Compliance (ORPC), the IACUC will evaluate such departures using the [PHS Policy](#) and the [Guide for the Use of Laboratory Animals](#) (the *Guide*). Reports of departures from the Guide will be identified specifically and reasons for each departure will be stated and will contain a reasonable and specific plan and schedule for correcting each departure. The ORPC staff, in cooperation with the UMBC Attending Veterinarian, will monitor the progress of the corrective actions to ensure completion according to the timeline included in the plan.

Post-IACUC Approval

Examples of departures to be reported include but are not limited to the following:

- Use of a procedure that might increase the pain/distress category in which the animals are placed, or might otherwise be considered a significant departure from the written protocol
- Use of a procedure not described in the protocol application
- Single housing of social animals
- Housing animals at temperatures outside the recommended ranges
- Sanitization schedules outside the recommended frequency
- Housing rodents without contact bedding

The reasons for all departures as well as a plan to correct the departures must be stated in the report. Reports of departures will undergo full committee review at a meeting of the IACUC. The IACUC will request information for modification prior to approval. Approved departures are documented in the meeting minutes and included in the semi-annual report sent to Dr. Karl Steiner (UMBC's Institutional Official [IO]).

Departures from the provisions of *the Guide* that are not approved by the IACUC prior to implementation are considered non-compliant with PHS Policy. Those departures will be promptly reported to OLAW and will subsequently be included in the semiannual report to the IO.

Pre-IACUC Approval

When investigators are creating a protocol application, keep the *Guide* and the above examples in mind as research procedures are developed. Procedures that contravene elements of *the Guide* must be justified and based on scientific merit, veterinary medical review, or animal welfare regulations and stated directly in the protocol. The IACUC will review all components related to the care and use of animals and determine that the proposed protocols are in accordance with *the Guide* and the PHS Policy and will request modification of the protocol procedures prior to approval. **NOTE:** when developing protocols, exceptions listed in *the Guide* are not considered departures.

Please do not hesitate to contact the ORPC at compliance@umbc.edu with questions or for more information.

Additional details are found in the OLAW/NIH document, Departures from the guide, <https://olaw.nih.gov/guidance/departures-from-the-guide.htm>.



TITLE: DESIGNATED MEMBER REVIEW	SOP NO.: IACUC 102
EFFECTIVE DATE: 12/4/2019	REVISION NO.: 00

1. PURPOSE

- 1.1. The purpose of this Standard Operating Procedure (SOP) is to provide a detailed description of procedures for Designated Member Review (DMR) followed by the IACUC as described in the Guide for Care and Use of a Laboratory Animals (the *Guide*) chapter 2 Pg.14-33, and PHS policy IV.C.2
- 1.2. UMBC Office of Research Protections and Compliance [ORPC] and its committee are responsible for the approval and implementation of this SOP

2. DEFINITIONS

- 2.1. IACUC- Institutional Animal Care and Use Committee
- 2.2. FCR- Full Committee Review
- 2.3. DMR- Designated Member Review

3. PROCEDURE

- 3.1. The IACUC *may* use Designated Member Review to process the following:
 - 3.1.1. A new protocol submission
 - 3.1.2. An amendment request



- 3.1.3. A revised protocol that was reviewed by the Full Committee and categorized as *Modifications Required to Secure Approval*.
- 3.1.3.1. If all members of the IACUC are present at a meeting, the committee may vote to require modifications to secure approval and have the revised research protocol reviewed and approved by DMR or returned for FCR at a convened meeting.
- 3.1.3.2. If all members of the IACUC are not present at a meeting, the committee may use DMR subsequent to FCR according to the following stipulations:
- 3.1.3.2.1. All IACUC members agree in advance in writing via email that the quorum of members present at a convened meeting may decide by unanimous vote to use DMR subsequent to FCR when modification is needed to secure approval. IACUC members are provided seven (7) days in which to respond to agree on using DMR subsequent to FCR. Members will send their response to the Office of Research Protections and Compliance. However, any member of the IACUC may, at any time, request to see the revised protocol and/or request FCR of the protocol.
- 3.2. Prior to using DMR process for protocols or amendments, the IACUC at large is polled as to whether DMR is appropriate. If any member objects to DMR, the submission will automatically be reviewed by FCR.
- 3.3. At least one IACUC member along with the attending vet is assigned by the Chairperson (or designee) to conduct the DMR. A protocol that has been revised post-FCR (see 3.1.3 above) can be automatically assigned by the ORPC, with the committee chair's approval, for DMR to one (or multiple) of the IACUC member(s) who originally reviewed the protocol and made the comments at a convened meeting. IACUC members can call for Full Committee Review (FCR) at any time. The designated reviewer(s) can take any of the following actions



- 3.3.1. Recommend Approval: The submission complies with all requirements of the Guide and PHS policy and is written in such a way that only administrative questions or clarifications are required.
- 3.3.2. Require Modifications to Secure Approval: The submission complies with all requirements of the Guide and PHS policy but is written in such a way that minor questions and/or clarifications must be resolved to secure approval.
- 3.3.3. Require Full Committee Review



TITLE: AUTOMATIC WATER RECOIL HOSE SANITIZING S.O.P.	SOP NO.: AH 605
EFFECTIVE DATE: 04/16/2020	REVISION NO.: 00

1. PURPOSE

- 1.1. The purpose of this Standard Operating Procedure is to assure proper sanitizing of automatic water recoil hoses. By sanitizing the automatic water recoil hoses, we provide a cleaner environment for the animals, which helps in maintaining good animal health and well-being.

2. RESPONSIBILITY

- 2.1. UMBC animal caretaking staff are responsible for the implementation this SOP. This SOP will be overseen and monitored by the UMBC animal facility manager.

3. MATERIALS AND EQUIPMENT

- 3.1. Automatic water recoil hose
- 3.2. Cage Washer

4. DEFINITIONS

- 4.1.- NA

5. PROCEDURE

- 5.1. Automatic water recoil hoses will be sanitized once every two weeks
 - 5.1.1. Disconnect the automatic recoil hose from the animal rack and replace it with a new sanitized water recoil hose.
 - 5.1.2. Bring the recoil hose to the cage washer
 - 5.1.3. Place the recoil hose in the cage washer in a safe and secure manner so not to damage the cage washer and hose while the cage washer is running.

5.1.4. Secure the cage washer door and run the cage washer on a stainless steel or rodent rack cycle- ensuring the cycle reaches 180 degrees.

5.1.5. At the completion of the cycle remove the recoil hose and store in a safe and secure location in a container so that the hose does not accrue dust.



TITLE: Cage Washer and Autoclave Temperature Validation SOP	SOP NO.: AH508
EFFECTIVE DATE: 04/16/2020	REVISION NO.: 00

1. PURPOSE

- 1.1. The purpose of this standard operating procedure is to provide assurance that the cage washer and Autoclave are reaching temperature during a cycle.

2. RESPONSIBILITY

- 2.1. UMBC animal husbandry staff are responsible for ensuring this SOP is properly executed. This SOP will be overseen and monitored by the UMBC husbandry manger.
- 2.2. Staff are not permitted to enter cage washers and autoclaves when powered on, nor are they permitted to walk through them as a means of crossing between load and unload sides, nor are they permitted to operate the equipment in an unsafe manner at any time. This directive is absolute and must be understood and accepted by all staff.

3. MATERIALS AND EQUIPMENT

- 3.1. Cage Washer
- 3.2. Autoclave
- 3.3. One-Time-Use Single-Point Temperature-Indicating Labels

4. DEFINITIONS

- 4.1. N/A

5. PROCEDURE



- 5.1. This procedure will be performed with the first cycle of the day to ensure that the cage washer and autoclave are reaching correct temperature for future loads.
 - 5.1.1. Turn the cage washer and or autoclave on and load a cage rack into the cage washer, or cages into the autoclave and select the correct cycle for the load.
 - 5.1.2. Attach a temperature-indicating label to the rack or cage stack.
 - 5.1.3. Close the door and execute the cycle.
 - 5.1.4. Wait for the cycle to be completed before opening the exit door and removing the clean cage/rack.
 - 5.1.5. Remove the temperature label from the rack or cage. If the label has turned black, then the cage washer/autoclave has achieved the proper temperature. If the label is white, the cage washer did not achieve proper temperature. If a white label is observed, place the rack back into the cage washer/autoclave placing a new label on the rack/cage. Shut the entrance door and run the load for a second time.
 - 5.1.6. If the label is black after the second run, then proper temperature has been achieved. If the label is still white, contact your supervisor and shut down the cage washer/autoclave until the manager can determine why the cage washer/autoclave is not reaching proper temperature.
 - 5.1.7. If the cage washer/autoclave has achieved temperature place the black temperature label in the logbook with your initials and date next to the dot. The logbooks will be stored in the cage washer room on the exit side in a secure, dry location.



TITLE: ASSESSING THE EFFECTIVENESS OF SANITATION	SOP NO.: AH 503
EFFECTIVE DATE: 04/16/2020	REVISION NO.: 00

1. PURPOSE

The purpose of this SOP is to monitor and assess the effectiveness of cage and rack washers, tunnel washers, and mobile manual sanitizing apparatus used to sanitize cages and racks, cage components, and surfaces of animal holding spaces.

2. RESPONSIBILITY

2.1. This SOP will be implemented and conducted by the UMBC animal facility manager.

3. MATERIALS AND EQUIPMENT

3.1. Replicate Organism Detection and Counting Press Plates with D/E neutralizing agar, culture swab samples transferred to media or other culture plates (e.g. Difco HyCheck)

4. DEFINITIONS

4.1. -NA

5. PROCEDURE

5.1. Areas to be monitored for sanitation effectiveness will be tested at least semi-annually or when visual indicators suggest that sanitation has not been effective.

5.2. Cage wash equipment in each facility will be evaluated through testing of facility typical cages and components (e.g. rodent cages for species that are housed in those facilities, toys and enrichment devices, etc.).

5.3. Testing will be conducted using RODAC (Replicate Organism Detection And Counting) press plates with D/E neutralizing agar, culture swab samples transferred to media, or other culture plates (e.g. Difco HyCheck) following manufacturers recommended procedures.

5.4. Culture is performed by a contract laboratory

6. RESULTS

6.1. Total CFUs will be reported for each unit or space and results interpreted as follows:

<i>CFUs</i>	<i>Effectiveness of Sanitation</i>	<i>Gram Stain</i>
0-10	Adequate	Gram Positive Cocci or Fungal
10-20	Marginal	
>20	Unsatisfactory	Gram Negative Cocci

6.2. Post-sanitize culture results showing more than 20 CFUs per plate or any Gram Negative colonies will be considered Unsatisfactory.

6.3. Any Unsatisfactory results will be scheduled for retest. Effected caging and equipment will not be used until test results are adequate

6.4. Repeat of Unsatisfactory results will require the equipment to be tagged and taken out of service (locked out). Equipment will then be evaluated for proper operation and any necessary repairs.

6.5. Once repairs are completed or malfunctions corrected, the unit will be retested. If the retest culture results are adequate the unit will be placed back in service.

7. REFERENCES

7.1. Microbial Monitoring Program, Quip Laboratories, Inc. 2009.

7.2. RODAC Plates product specification sheet, #8835631J1AA, BBL, 2005.

7.3. Weisbroth, Laboratory Animal Facility Sanitation, Lab Animal 11(2):25-26, 1982.

7.4. APHA, Committee on Microbial Contamination of Surfaces, 1970.

5.2.4. Use up to 3 indicators (1 in each cage of diet) per sterilizer load. No more than 3 for that load.

5.2.5. Process the diet on the defined cycle used for this purpose.

5.3. Biological Indicator Retrieval and Incubation.

5.3.1. Once the sterilized cages are removed and allowed to cool; remove the EZ Test biological indicators from each cage in an aseptic manner (e.g. in a biological safety cabinet using aseptic technique used for cage changing).

5.3.2. Do not use the diet until the test results are reviewed and recorded. It is important to prepare diet in advance to allow for the load to be validated.

5.3.3. Turn on the incubator and allow it to heat up. The temperature should reach 60°C.

5.3.3.1. If the incubator does not reach 60°C, immediately contact your manager

5.3.4. Check the chemical indicator on the label of the EZ Test Biological Indicators to ensure that it changed from blue to black (this indicates that it was exposed to steam; and only used to distinguished exposed to unexposed does not indicate acceptable sterilization)

5.3.5. Place the EZ Test biological indicator in the upright position in the white plastic crusher and gently squeeze to break the glass ampoule. (This must be done with each EZ Test biological indicator)

5.3.6. Place the biological indicators in the incubator wells immediately after crushing glass ampoule.

5.3.7. Take an unsterilized EZ Test biological indicator and follow the same procedure of breaking glass ampoule; then place in the incubator well marked with a "C" as a positive control.

5.3.8. Incubate the biological indicators for 24 hours.

5.3.8.1. Check the biological indicators at 24 hours. If any of the indicators turn positive (yellow or turbid), immediately contact your Supervisor.

5.3.9. Evaluate the biological indicator fluid color/clarity.

5.3.9.1. **Positive (+) = growth present, yellow in color or turbid.**

5.3.9.2. **Negative (-) = no growth present, fluid is purple in color, not turbid.**

5.3.9.3. If the fluid is yellow in color or turbid (cloudy), this means the load failed.

5.3.9.4. If the fluid is purple in color, this means the test passed and the diet can be used.

5.3.9.5. If the positive control does not turn yellow or turbid, immediately contact your manager for evaluation.

5.4. Biological Indicator Documentation.

5.4.1. Record the findings of the test on the Autoclave Cycle Validation by Biological Indicators log.

5.4.1.1. Use one line for the results of the validation test.

5.4.1.2. Indicate the date of sterilization, the incubation date and the number of biological indicators that were positive (yellow or turbid) or negative (purple) by entering the number to the LEFT of the positive (+) or negative (-) symbols for both the control indicator and the test indicators.

5.4.1.3. Initial the log at each line once the results are entered.

5.5. Biological Indicator Disposal

5.5.1. Once the results are recorded, remove the biological indicators from the incubator and dispose of in a sharps container.

5.6. Positive Test Results

5.6.1. If ANY of the test biological indicators are positive (yellow or turbid), you must contact your manager immediately before using the product.

6. RESULTS

6.1. Total CFUs will be reported for each unit or space and results interpreted as follows:

<i>CFUs</i>	<i>Effectiveness of Sanitation</i>	<i>Gram Stain</i>
0-10	Adequate	Gram Positive Cocci or Fungal
10-20	Marginal	
>20	Unsatisfactory	Gram Negative Cocci

6.2. Post-sanitize culture results showing more than 20 CFUs per plate or any Gram Negative colonies will be considered Unsatisfactory.

6.3. Any Unsatisfactory results will be scheduled for retest. Effected caging and equipment will not be used until test results are adequate

6.4. Repeat of Unsatisfactory results will require the equipment to be tagged and taken out of service (locked out). Equipment will then be evaluated for proper operation and any necessary repairs.

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7.4. APHA, Committee on Microbial Contamination of Surfaces, 1970.



DEPARTMENT OF HEALTH and HUMAN SERVICES

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December 19, 2019

Re: Assurance # D16-00462 (A3784-01)

Karl V. Steiner, Ph.D.
Vice President of Research
University of Maryland, Baltimore County
1000 Hilltop Circle
Baltimore, Maryland 21250

Dear Dr. Steiner,

On behalf of the Office of Laboratory Animal Welfare (OLAW) we would like to thank (b) (6) as well as you and your staff for the hospitality extended to us during the OLAW Division of Assurances site visit of your animal care and use program on December 3, 2019. 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 and effort put forth by you, the Associate Vice President for Research, and the many individuals we had the pleasure of meeting during the site visit. We thank those who coordinated logistics, escorted us throughout the day, answered questions and provided documentation. We especially want to thank the Clinical Veterinarian; the Compliance Officer; the IACUC Chairperson; IACUC Administrators; and IACUC Members for their participation in the site visit.

We noted particular program elements that were commendable including:

- Excellent support from upper management;
- The opening session revealed good communication and a team approach to oversight of the animal care and use program;
- Animal care personnel that were forthcoming and knowledgeable;
- Active participation of non-affiliated and non-scientific IACUC members;
- All rodents and aquatics were found to be in good health and well cared for;
- The fish facility in the Biology building was clean, organized and well managed;
- All animals are provided species appropriate enrichment;
- Animals are socially housed when appropriate;
- Room logs are thorough and complete in the Biology building;

- The CO2 euthanasia chambers were equipped with appropriate restrictor mechanisms and regulators. As a result, the system can provide the correct flow rate with no additional adjustments required;
- An adequate training program and documentation of employee/IACUC member participation in the training;
- The Occupational Health and Safety Program appears to be comprehensive; personnel are enrolled and are aware of the options available to them;
- The protocol review system captures all comments and questions from all reviewers in one easy to reference location;
- The new vivarium appears to be state of the art (there is no animal occupancy currently);
- Considering the apparent age of the facilities, the physical plant operations regarding the animal research program appear to function sufficiently.

Some areas for which we require additional information include the following:


- “The *attending veterinarian* (AV) is responsible for the health and wellbeing of all laboratory animals used at the institution. The institution must provide the AV with sufficient authority, including access to all animals, and resources to manage the program of veterinary care. The AV should oversee other aspects of animal care and use (e.g., husbandry, housing) to ensure that the Program complies with the *Guide*,” *Guide* page 14.
The AV should provide support, direction and guidance to the administration and management of the animal program.
- The Assurance describes the following – “The Veterinarian” is present at the institution an average of approximately 10 hours per month. In addition, “The Veterinarian” contributes on average approximately 10 hour per month to the program while off-site reviewing protocols and providing consultation on various program related topics. Provides advice on policies and procedures, experimental animal models, animal welfare, occupational health, hazard containment, and zoonosis control programs. Oversees activities of the animal care program supervisor and personnel. Reviews and inspects the housing and care of animals in each facility on a monthly basis and at each scheduled semi-annual inspection.” It was not clear that what is described in the Assurance is occurring at the Institution.
- “The IACUC... is responsible for assessment and oversight of the institution’s Program components and facilities. It should have sufficient authority and resources (e.g., staff, training, computers and related equipment) to fulfill this responsibility. The committee is responsible for oversight and evaluation of the entire Program and its components as described in other sections of the *Guide*. Its oversight functions include review and approval of proposed animal use (protocol review) and of proposed significant changes to animal use; regular inspection of facilities and animal use areas; regular review of the Program; ongoing assessment of animal care and use; and establishment of a mechanism for receipt and review of concerns involving the care and use of animals at the institution,” *Guide* pages 14 and 25. The IACUC should increase the level of program oversight and direction regarding the laboratory animal facility administration and management.
- The animals housed in the Psychology building are not observed on weekends and holidays. In addition, the animal room log sheets are not completed. Animals should be observed daily. “Animals should be cared for by qualified personnel every day, including weekends and holidays, both to safeguard their well-being and to satisfy research requirements,” *Guide* page 74.
- Re-evaluate departures from the *Guide*. The Assurance describes that there are no departures from the *Guide*. The IACUC meeting minutes documented that there were no departures from the *Guide*. However, an IACUC approved protocol for food restriction was identified, which is a departure from the *Guide* requiring scientific justification and review approval by the IACUC.
- Regarding protocol review by the Full Committee when the outcome is “requires modifications to secure approval,” it was not clear that the process conducted is consistent with the *PHS Policy*. Please re-evaluate the procedures used when the IACUC reviews the revised protocol to be consistent with the *PHS Policy*.

- The outcomes and votes of two protocols are not documented in January and October 2019 minutes, the *PHS Policy IV.E.1.b* requires documentation of committee deliberations;
- No signage for reporting animal welfare concerns was identified in facilities. Develop a system for reporting animal welfare concerns.
The Assurance describes the following – “Notices are located in the animal facilities advising individuals how and where to report animal welfare concerns and stating that any individual who, in good faith, reports an animal welfare concern will be protected against reprisals”.
“Mechanisms for reporting concerns should be posted in prominent locations in the facility and on applicable institutional websites with instructions on how to report the concern and to whom ... the process should include a mechanism for anonymity, compliance with whistle blower policies ... protection from reprisals,” *Guide* page 23-24;
- It was not evident that accounting for rodent pups is consistent with OLAW guidance. Animals should be accounted for on some protocol 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 from approved animal numbers for each IACUC protocol.
- It was not clear that animal numbers are being tracked against the approved protocol. Develop centralized animal procurement and a tracking mechanism to ensure incoming animals are accounted for on an approved protocol.
- For the new vivarium, develop a comprehensive mechanism for tracking “Vet Health-Check” notices.
- Develop a mechanism to sanitize automatic watering recoil hoses;
- There are no logbooks maintained for monitoring cagewash and autoclave temperatures during operation. Develop a mechanism to document appropriate sanitation;
- There is no microbiological monitoring of racks and cages following cage wash. Also, there is no monitoring following room sanitation; Develop mechanism for ensuring effective sanitation. “Whether the sanitation process is automated or manual, regular evaluation of sanitation effectiveness is recommended. This can be performed by evaluating processed materials by microbiologic culture or the use of organic material detection systems (e.g., adenosine triphosphate [ATP] bioluminescence) and/or by confirming the removal of artificial soil applied to equipment surfaces before washing,” *Guide* page 73.
- OLAW encourages development of SOPs for BSL2 procedures prior to opening new facility;
- While we did not locate an SOP on processes for the care of the zebra fish, the room log had a morning and afternoon log sheet for documenting procedures. For the last few months (July – November 2019) only the afternoon sheet was being completed. This may not be consistent with your own SOPs.

Please provide an update to OLAW on the items listed above by March 30, 2020. Thank you once again for your time and hospitality in hosting the OLAW site visit.

Sincerely,

12/19/2019

 Venita B. Thornton

Venita B. Thornton, DVM, MPH

Signed by: PIV

Venita B. Thornton, DVM, MPH

Senior Assurance Officer

Division of Assurances

Office of Laboratory Animal Welfare, NIH

cc: IACUC Chairperson
Attending Veterinarian
Axel Wolff, Deputy Director, NIH/OLAW
Eileen Morgan, Director, Division of Assurances, NIH/OLAW



DEPARTMENT OF HEALTH & HUMAN SERVICES

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Home Page: <http://grants.nih.gov/grants/olaw/olaw.htm>

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Telephone: (301) 496-7163

November 20, 2019

Reference Assurance: #D16-00462 (A3784-01)

Karl V. Steiner, Ph.D.
Vice President of Research
University of Maryland, Baltimore County
1000 Hilltop Circle
Baltimore, Maryland 21250

Dear Dr. Steiner:

On behalf of the Office of Laboratory Animal Welfare (OLAW), I am writing to inform you that we are planning a visit to the University of Maryland - Baltimore County, on December 3, 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, Ms. Eileen Morgan, Ms. Paula Knapp and Axel Wolff, DVM, MS. 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 four semiannual program review and facility inspection reports.
- The USDA reports from 2014 to the present, if applicable.
- The minutes of the three most recent IACUC meetings.
- Standard Operating Procedures for your animal program, such as those relevant to husbandry, anesthesia, enrichment 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.
- The most recent communication regarding your AAALAC International Accreditation.

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 send me a proposed agenda for review and acceptance for a visit beginning on Tuesday, at approximately 8:30 a.m. and your facility entry requirements, as well as, instructions for local parking and directions to an initial meeting site.

Additionally, please provide a current facility and species inventory form by building along with a list of laboratories or procedure areas where vertebrate animal work is performed outside the facilities. Please feel free to contact me at (301) 451-4208 and we can discuss the plan for OLAW's visit.

Sincerely,

11/20/2019

X Venita B. Thornton

Venita B. Thornton, DVM, MPH

Senior Assurance Officer

Signed by: PIV

Venita B. Thornton, DVM, MPH

Senior Assurance Officer, Division of Assurances

Office of Laboratory Animal Welfare, NIH

Cc:

Charles Bieberich, Ph.D. - IACUC Chairperson

(b) (6)

Machado, Susann (NIH/OD) [E]

From: Machado, Susann (NIH/OD) [E]
Sent: Wednesday, November 20, 2019 10:27 AM
To: steinerk@umbc.edu
Cc: bieberic@umbc.edu; (b) (6) Thornton, Venita (NIH/OD) [E]; OLAW Division of Assurances (NIH/OD)
Subject: Site Visit Request-UMBC-D16-00462-Legacy #A3784-01-December 2019
Attachments: Site Visit Request- UMBC-#D16-00462 (A3784-01)- December 2019.pdf

Follow Up Flag: Follow up
Flag Status: Completed

Categories: Dr. Thornton, Sue

Dear Dr. Steiner,

On behalf of the Office of Laboratory Animal Welfare (OLAW), I am writing to inform you that we are planning a visit to the **University of Maryland - Baltimore County, on December 3, 2019**

Please contact Dr. Venita B. Thornton regarding a proposed agenda for a visit beginning at approximately **8:30 a.m. on Tuesday, December 3, 2019** and instructions for parking, your facility entry requirements, as well as directions to an initial meeting site. Additionally, please provide a current facility and species inventory form

Please feel free to contact Dr. Venita B. Thornton at 301- 451-4208 to discuss the entry requirements and the plan for OLAW's visit.

Thank you, Sue



Susann Machado, D.D.
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To look into the eyes of a wolf is to see your own soul-hope you like what you see - Aldo Leopold
