

## **Animal Welfare Assurance for Domestic Institutions**

I, Truell W. Hyde, PhD, Vice Provost for Research, as named Institutional Official for animal care and use at Baylor University, provide assurance that this Institution will comply with the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (Policy).

### **I. 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 a different name:  
Baylor University Waco Campus, Waco, Texas
- B. The following are other institution(s), or branches and components of another institution:  
None.

### **II. Institutional Commitment**

- A. This Institution will comply with all applicable provisions of the Animal Welfare Act and other Federal statutes and regulations relating to animals.
- B. This Institution is guided by the "U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training."
- C. This Institution acknowledges and accepts responsibility for the care and use of animals involved in activities covered by this Assurance. As partial fulfillment of this responsibility, this Institution 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, and other applicable laws and regulations pertaining to animal care and use.
- D. This Institution has established and will maintain a program for activities involving animals according to the most recent edition of the *Guide for the Care and Use of Laboratory Animals* (Guide).
- E. This Institution 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.

### **III. Institutional Program for Animal Care and Use**

- A. The lines of authority and responsibility for administering the program and ensuring compliance with the PHS Policy are shown in Attachment: Lines of Authority and Responsibility.

B. The qualifications, authority, and percent of time contributed by the veterinarian(s) who will participate in the program are as follows:

1) Name: Ryan Stoffel

Qualifications

• Degrees:

PhD in Veterinary Pathobiology (2011), University of Missouri  
Residency – Comparative Medicine (2006-2009), University of Missouri  
DVM (2006), University of Wisconsin  
BS in Animal Science (2001), University of Wisconsin

• Training or experience in laboratory animal medicine or in the use of the species at the institution:

Dr. Stoffel joined the institution as full-time attending veterinarian for the program in September 2016. Prior to joining the institution, he was an Associate Research Animal Veterinarian at the University of Wisconsin-Madison from 2011-2016. He was the senior program veterinarian for two research programs and provided veterinary care and oversight to research animals including rodent, aquatic, and avian species within those programs. He was a voting member of the IACUC. During his Comparative Medicine Residency from 2006-2009, he provided veterinary care and oversight to large and small research animals and supplied technical training and assistance to animal users, including researchers, graduate students, and animal care staff. In July 2018, Dr. Stoffel became ACLAM Board Certified.

Authority: Dr. Ryan Stoffel has direct program authority and responsibility for the Institution's animal care and use program including access to all animals.

Time contributed to program:

Dr. Stoffel is a full-time employee. The percentage of time contributed to the animal care and use program is 100%.

In the event that Dr. Stoffel is unavailable, back-up is available to provide routine and emergency care. Backup veterinary service and needs will be provided by (b) (6) DVM who is employed full-time as the veterinarian of Robinson Drive Animal Hospital in Robinson, TX. (b) (6) performed the role of consulting veterinarian for the Institution's animal care and use program until 2016.

C. The IACUC at this Institution is properly appointed according to PHS Policy IV.A.3.a. and is qualified through the experience and expertise of its members to oversee the Institution's animal care and use program and facilities. The IACUC consists of at least 5 members, and its membership meets the composition requirements of PHS Policy 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.

D. The IACUC will:

1) Review at least once every 6 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:

Every six months, the IACUC reviews the Institution's program at the IACUC convened meeting following the completion of facility inspections. This is so the inspection results can be discussed in the context of the Program Review. Each participating member is provided with Semiannual Program Review Checklist available on the OLAW web site as a guide to ensure all program areas requiring review are covered, as well as other reference materials as needed, and the members may refer to the most recent edition of the *Guide* as basis for their evaluations. Each section of the Semiannual Program Review Checklist is assigned to at least 2 members to ensure the key elements of program review are addressed. However, all committee members are invited to review and comment on any section of the Semiannual Program Review Checklist. IACUC concerns



and recommendations documented in past Reports are reviewed to determine how they were addressed, and whether Institutional Official or IACUC Chair follow-up is needed. The formal program review is conducted at a convened IACUC meeting and includes discussion of the committee's findings and recommendations. The members assigned to each section of the Semiannual Program Review Checklist present their findings for discussion and resolution if needed. All committee members are invited to discuss and comment on each section. Committee findings and recommendations are captured in the minutes for the convened meeting. The key elements reviewed include Institutional Policies and Procedures and Veterinary Care. Institutional policies and procedures reviewed include IACUC-01 Animal Care and Use Program and IACUC-02 The Institutional Animal Use and Care Committee. Also, policies and procedures regarding criteria for approval, the review process for FCR, DMR, VVC, and administrative functions, and amendments are reviewed. The University, (b) (4) and (b) (4) disaster plans are reviewed. The IACUC reviews current requirements for personnel qualifications and training and the occupational health and safety program. The IACUC also reviews the Veterinary Care plan which includes its management; the procurement, transportation, and clinical care of animals; policies and procedures on assessing pain and distress and the selection and monitoring of anesthesia and analgesia as well as drug storage and control; and policies and procedures on euthanasia.

- 2) Inspect at least once every 6 months all of the Institution's animal facilities, including satellite facilities and animal surgical sites, using the *Guide* as a basis for evaluation. The IACUC procedures for conducting semiannual facility inspections are as follows:  
Every six months, the at least two committee members are assigned to inspect each facility. The Office of Research Compliance (ORC) schedules the inspection and the date and time are announced to the committee. All committee members are invited to participate in the inspection. At the appointed date and time, the assigned members and any other available IACUC members tour the facility. The inspections are based upon an inspection checklist derived from the Sample Semiannual Facility Inspection Checklist available on the OLAW web site to address the key inspection elements applicable to our institution. The checklists are collected by the ORC staff and collated into a facility report. The key elements reviewed and inspected include: Terrestrial Animal Housing and Support Areas; Aquatic Animal Housing and Support Areas; Cagewash; Aseptic Surgery Facilities; Procedure Areas; Non-survival Surgery Facilities; Behavioral Studies Areas; Laboratories; and Hazardous Agent Containment. (Note: Imaging and Whole-Body Irradiation is not conducted at the institution.)
- 3) Prepare reports of the IACUC evaluations according to 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:  
The ORC collects the checklists from the IACUC members who participated in the facility inspections. ORC staff analyze the checklists and compile a facility report. The facility reports are then evaluated by the IACUC Chair. The facility reports are circulated to the committee members for comments and corrections. The reports are revised to reflect the consensus of the committee. Minority views are recorded in the report. The facility reports are sent to the Institutional Official with a copy to each facility director. Any deficiencies noted in the facility reports are included in the semiannual report. Individual facility reports are not shared with the IO unless the IO requests the reports.

A semiannual report of the IACUC's Program Review is developed and sent to the Institutional Official. It contains: the description of the nature and extent of the institutions adherence to the *Guide* and PHS Policy; identification of any deficiencies in the program or facility; minority views of the IACUC; Identification of facilities accredited by AAALAC; and the signatures of a majority of the IACUC members. The ORC, in conjunction with the IACUC Chair, drafts the report and circulates it to the committee for comments and suggested changes. The ORC revises the report based on committee feedback and re-circulates to the committee for review. Minority views are recorded in the report, a final version is signed by at least a majority of committee members, and then is sent to the Institutional Official by the ORC.



In the event that the IACUC determined it necessary to depart from the provisions of the *Guide*, PHS Policy, or the AWA, the departure would be included in the semiannual report to the Institutional Official, along with the rationale for the departure.

If deficiencies are identified in the program or in the facility inspections, the IACUC reports the deficiencies to the Institutional Official with recommended remedies and proposed time frame for correction. The committee differentiates between minor and significant deficiencies in the semiannual report. The ORC, in conjunction with the IACUC Chair, is responsible to follow up with facility directors and/or researchers to ensure any deficiencies have been appropriately resolved.

- 4) Review concerns involving the care and use of animals at the Institution. The IACUC procedures for reviewing concerns are as follows:

Individuals are encouraged to report any concerns to the IACUC chair, to any IACUC committee member, to the Attending Veterinarian, or to the Office of the Vice Provost for Research - Office of Research Compliance. Signs are posted in animal facilities providing contact information for reporting. Additionally, the university utilizes EthicsPoint to allow for anonymous and confidential reporting of activities that may involve criminal, unethical, or otherwise inappropriate behavior in violation of Baylor University's policies. Concerns can be reported verbally (in-person or phone) or in writing (paper or electronic). All reports are held in the strictest confidence allowable. The chair and/or the Assistant Vice Provost for Research, Director of Compliance will investigate and evaluate the report. At the end of the investigation, a report of findings is created and submitted to the Institutional Official and the committee. If the investigation concludes that a violation of institutional policy, PHS Policy, the *Guide*, and/or the AWA occurred, a remedy to correct the violation and to ensure future compliance is implemented. The chair and/or a designee from the Office of the Vice Provost for Research is responsible for following up to make sure the issue is resolved. The finding and resolution is reported to OLAW.

Baylor University maintains a Whistleblower Policy (BU PP 037). The Whistleblower Policy protects any individual who makes a protected disclosure. More specifically it:

1. encourages individuals to make a protected disclosure so that prompt corrective action can be taken by the university,
2. informs individuals how to make a protected disclosure,
3. protects individuals from retaliation for having made a protected disclosure (individuals who self-report their own misconduct are not afforded protection by this policy), and
4. provides individuals who believe they have been subject to retaliation or false allegations a fair process to seek relief from these acts.

- 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:

In most cases, any recommendations are made as part of the semiannual report to the Institutional Official. If any issue occurs outside of the semiannual review and requires immediate resolution, a recommendation is made directly from the IACUC chair and/or the Assistant Vice Provost of Research, Director of Compliance to the Institutional Official. Additionally, the Assistant Vice Provost for Research, Director of Compliance attends all meetings of the committee and is aware of all activities of the committee.

- 6) Review and approve, require modifications in (to secure approval), or withhold approval of PHS-supported activities related to the care and use of animals according to PHS Policy IV.C.1-3. The IACUC procedures for protocol review are as follows:

All IACUC submissions are processed through an electronic management system, which is administered by the Office of the Vice Provost for Research - Office of Research Compliance (ORC). Upon receipt, ORC staff will conduct a preliminary review and communicate with the principal investigator concerning any administrative or minor



issues. Once these are resolved, the submission is forwarded electronically to the IACUC chair. The chair and the Attending Veterinarian (if requested by the Chair) will evaluate the submission and work with the principal investigator to address any major deficiencies in order to make sure that the information needed by the committee to properly evaluate the proposed animal use is included. Upon resolution, the submission is electronically shared with all committee members who will receive an electronic notice to review the submission.

Submissions that are in the USDA categories D and E are required to receive full committee review (FCR). If the submission calls for the use of animals under USDA Classification B or C, the committee members are polled to determine if Designated Member Review (DMR) may be used. DMR is utilized only after all members have been provided sufficient opportunity to call for FCR. Members are given five (5)-business days to request FCR review of a submission. If no member calls for FCR, then the submission is reviewed under DMR procedures. However, if even a single member requests FCR, the submission is placed on the next board meeting agenda for FCR. The IACUC only utilizes FCR and DMR review processes; no other form of protocol review (such as an expedited review process) is provided.

For DMR, the chair appoints one or more qualified committee members to review the submission. If a committee member has a conflicting interest in the submission, the chair shall not appoint him/her as a designated reviewer. The designated reviewer(s) may approve the submission, required modifications to secure approval, or refer the submission to FCR. DMR may not result in disapproval of a submission. If more than one reviewer is designated, the reviewers' decision must be unanimous. They will 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. If the reviewers recommend different decisions or modifications, they must come to a consensus or refer the submission to FCR.

FCR takes place at a convened meeting when a quorum of the committee is present. For each FCR submission, the committee may vote to approve, require modifications to secure approval, or disapprove. The vote outcome is determined by a majority vote of the quorum present. If the committee requires modifications, the members will differentiate between substantive and minor revisions as described in the *Guide*. Substantive revisions are required if the information provided in the proposal is insufficient to evaluate the submission. If methods are unclear, animal numbers are inconsistent, or justifications are insufficient, substantive revisions would be required. Simple corrections of typographical or numerical errors are considered minor revisions. When only minor revisions are required, the committee relies on the chair to review the modifications prior to final approval being granted.

When substantive modifications are required to secure approval, the quorum of members present at the convened meeting may decide by unanimous vote to use DMR subsequent to FCR to review the required modifications in order to grant final approval. This written agreement is documented in the IACUC-approved SOP titled IACUC-04: Protocol Review Process. The DMR process for review of required modifications follows the same guidelines as described in this section. However, any member may, at the time of the convened meeting or at the time of the DMR polling process, request to see the revised submission and/or request FCR of the revisions.

If a member has a conflict of interest on a submission for review at a convened meeting, the member must recuse him- or herself and leave the room during the committee's discussion and vote. The member can answer questions or provide additional information to the other members prior to leaving the room. Upon recusal, the member with the conflict no longer counts towards quorum and thus, the remaining members present must meet quorum requirements. After the committee has voted, the recused member is invited back into the meeting and counts towards quorum. If, due to a member's recusal,



the remaining members do not create a quorum, the submission cannot be voted on and will be held over to the next convened meeting or reviewed via DMR if allowable.

Each submission and all subsequent modifications are maintained in an electronic management system and are available for review by all members at all times during a review process.

- 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 according to PHS Policy IV.C. The IACUC procedures for reviewing proposed significant changes in ongoing research projects are as follows:

Proposed changes are submitted to the IACUC via the electronic management system administered by ORC. The chair will evaluate the proposed changes and may approve minor changes on behalf of the committee. If significant changes are proposed, the chair will refer the submission to the committee or may require the principal investigator to submit a new study submission. The committee considers significant changes to include, but not limited to: changes to the study objectives; a change from non-survival to survival surgery; changes that result in greater pain, distress or degree of invasiveness; changes in the species; a change in principal investigator; change in housing and/or use of animals in a location that is not part of the animal program overseen by the IACUC; or changes that impact personnel safety. Proposed significant changes are reviewed using the same processes as those described in Part III.D.6 for new submissions.

There are also certain modifications that can be handled in consultation with the Attending Veterinarian (AV) through a Veterinary Verification and Certification (VVC) process. The AV will determine at his/her discretion which modifications meet the criteria for this level of review. The criteria are: changes in anesthesia, analgesia, sedation, or experimental substances; changes in euthanasia techniques to any method approved in the AVMA Guidelines for the Euthanasia of Animals; and changes in the duration, frequency, type, or number of procedures performed on an animal which do not increase the potential for pain or distress experienced by the animal. A policy with evaluation criteria has been created and approved by the IACUC and the VVC process is documented in the record of the modified protocol.

A significant change that may be handled administratively with additional consultation or notification is an increase in previously approved animal numbers. This administrative review and approval is conducted by the IACUC Chair. The increase is not to exceed 20% for non-USDA regulated species is permitted. The original rationale for the number of animals to be used must support the requested change; if not, an expanded rationale will be required. The change is documented through the submission of an amendment request that is maintained in the electronic management system administered by ORC. This policy is contained in IACUC-approved SOP IACUC-05: Amendments to Approved Protocols. This policy is compliant with NOT-OD-14-126: Guidance on Significant Changes to Animal Activities.

The IACUC interprets non-significant changes to mean those that do not have the potential to impact substantially and directly on the health and well-being of the animals. Such changes can be handled administratively by ORC Staff without IACUC-approved policies, consultations, or notifications. These changes include: correction of typographical errors; correction of grammar; contact information updates; change in personnel, other than the PI (Note that, there will be an administrative review to ensure that all such personnel are appropriately identified, adequately trained and qualified, enrolled in occupational health and safety programs, and meet other criteria as required by the IACUC.); or in the use of a new vivarium housing location.

- 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 according to PHS Policy IV.C.4. The IACUC procedures to



notify investigators and the Institution of its decisions regarding protocol review are as follows:

The decision to approve, require modifications to secure approval, or to withhold approval is communicated in writing through the electronic management system administered by ORC. If appropriate, a copy is submitted to the Institutional Official and the Office of Sponsored Programs for inclusion in grant applications and reports. Modifications required to secure approval are explicitly listed in the communication. If approval is withheld, the communication will contain the reasons for the decision. The principal investigator may address those reasons either in writing or in person at a meeting of the committee and request a new review based on his/her response.

- 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 at least once every 3 years according to PHS Policy IV.C.1.-5. The IACUC procedures for conducting continuing reviews are as follows:

The IACUC approves protocols for a period of three years, pending successful annual review. For annual review on the first and second anniversaries, the principal investigator must provide the committee with information indicating the active status of the research, certification that the currently approved methodology and procedures are being used, and confirmation on the number of animals, source(s) of the animals, housing location, and procedure location. For non-USDA covered animals, the chair reviews the annual reports, asks questions of investigator if needed, and if satisfactory, renews the approval for another year. The chair may also decide to send the annual reports for DMR or FCR review as described in Part III.D.6. For USDA-covered species, DMR review as described in Part III.D.6 is used. For USDA-covered species, late annual reports are not accepted and if annual review does not occur prior to the approval anniversary, the approval expires and the research must be re-submitted for review. On the third anniversary, the approval expires and the research must be submitted to the IACUC for a de novo review. The process for the de novo review is the same as the initial review of a submission as described in Part III.D.6. If the original protocol's approval expires while the replacement protocol is being reviewed, no use of animals according to the expired protocol can be conducted until the de novo submission is approved.

The IACUC monitors approved ongoing activities through scheduled semiannual facility inspections, annual review and triennial de novo review of approval protocols, review of amendment requests for approved protocols, and frequent communication with the AV and animal facility staff.

- 10) Be authorized to suspend an activity involving animals according to PHS Policy IV.C.6. The IACUC procedures for suspending an ongoing activity are as follows:

A decision to suspend an approved activity using animals requires a majority vote of a convened quorum of the IACUC. Criteria and timelines for resolution of the matter are recorded in the minutes along with the outcome of the vote to suspend and any minority views. A written communication of the decision is sent to the principal investigator and the Institutional Official (IO). The IO, in consultation with the IACUC, reviews the reasons for the suspension and the actions required to have the suspension lifted. The IO may impose additional conditions for lifting the suspension. Matters that fall under PHS Policy VI.F.3. will be reported promptly to OLAW. The IO will send a preliminary report to OLAW and, once action has been taken, the IO will send a final report to OLAW describing the reason(s) for the suspension, a full explanation of the circumstances, and measures that were taken to address the problem.

- E. The risk-based occupational health and safety program for personnel working in laboratory animal facilities and personnel who have frequent contact with animals is as follows:

The occupational health and safety program for animal users at this institution is a collaborative effort between the IACUC, the Department of Environmental Health & Safety (EHS), and the Office of Research Compliance (ORC). EHS maintains an *ex officio* position on the IACUC, attends all committee meetings, and reviews all submissions. EHS is responsible for maintaining the occupational health and safety program associated with animal use and



care. This includes reviewing research protocols to identify hazards, ensuring SOPs are developed when appropriate, providing and monitoring safety training, conducting semiannual safety inspections and investigating accidents (including animal bites). All faculty, staff, and students (including summer students and visiting faculty) who come in contact with research animals must complete the requirements of the Animal Worker Occupational Health & Safety Program (OHSP) provided by EHS.

The Animal Worker OHSP provides training on risk assessment, PPE, standard operating procedures, facilities, medical evaluation, and preventive medicine. Topics also include the following:

- Potential hazards and exposures when working with animals. Topics include: physical hazards, chemical hazards, biological hazards, animal biosafety levels, and antibiotics and controlled substances.
- Animal and latex allergies. Topics include: animal allergy, latex gloves and related allergies.
- Decontamination procedures and animal laboratory waste.
- Zoonosis related to mice and rats, rabbits, birds, fish and amphibians, and bats. Zoonosis issues with field studies is discussed.
- Best safety practices when working with research animals. Thirteen best practices are covered, including personal hygiene.
- Personal Protective Equipment (PPE). Details the type of PPE required, training, and roles and responsibilities.
- Preventing Asthma in Animal Workers. NIOSH publication is presented.

Additionally, all animal workers must complete: web-based training "Health and Safety for Personnel with Laboratory Animal Contact" and all appropriate web-based CITI program training as required by the IACUC for animal research (see section G); a risk assessment evaluation form; and a medical history questionnaire. This information will be sent for medical review and consultation to an outside party and recommendations for the individual worker will be returned to EHS. Recommendations include clearance to work with animals, denial of clearance, or provisional clearance provided resolution of follow-up items which may include physical examination, tetanus/diphtheria vaccination (required within 5 years), rabies vaccination (if appropriate), hearing or pulmonary function evaluation, respirator clearance tuberculosis screening or other appropriate measures. Annual re-enrollment in the Animal Worker OHSP is required for all faculty, staff, and students who have or will have contact with research animals.

Individuals are directed to enroll in the Animal Worker OHSP through the EHS website or by contacting the EHS department. Program information, policies, and all related forms are available for download. The Laboratory Safety and Biosafety Manuals provide institutional policies concerning safety practices, including personal hygiene. All Faculty and Staff are required to complete annual Laboratory Safety Training modules covering general laboratory safety. Institutional policies regarding personal hygiene in animal areas include:

- Never eat, drink, smoke, handle contact lenses, apply cosmetics, or take or apply medicine in areas where research animals are kept. Food and beverages cannot be stored or consumed in the laboratory. Never wear or bring lab coats or jackets into areas where food is consumed.
- Remove gloves and wash hands after handling animals or tissues derived from them and before leaving areas where animals are kept.
- Wear the required PPE and proper lab attire in all areas within the animal facility. Lab coats must be worn whenever working with laboratory animals. Lab coats used during animal work cannot be worn/used outside of the animal facility. Lab coats and other animal facility dedicated clothing (such as scrubs) are laundered in the animal facility which is equipped with appropriate laundry machinery. Disposable outer garments (i.e., Tyvek suits) may be useful when cleaning and decontamination of reusable clothing is difficult. Animal workers must follow institutional lab attire policy. Closed-toed shoes should be worn at all times. Steel-toed safety shoes may be necessary when there is a risk of heavy objects falling or rolling onto the feet, such as in bottle-washing operations or animal care facilities.



The institution recognizes that other personnel, such as maintenance, housekeeping, and police/security, may enter areas where research animals are kept. These personnel are not required to participate in the Animal Worker OHSP. There are signs outside the facility with appropriate contacts and a Restricted Access sign with a list of authorized personnel. All police/security personnel who need access will be accompanied by the animal facility supervisor, the Director of the (b) (4) or other animal facility authorized personnel. These personnel will be escorted in the facility at all times. The Baylor University Police Department is provided with emergency contact information to be used if there is an emergency involving animals at Baylor at times when the facility is not staffed (nights/weekends). The contact list includes:

- BU veterinarian
- Animal facilities staff
- ORC staff (Vice Provost for Research, Assistant Vice Provost for Compliance)
- IACUC chair
- Animal facility staff at collaborating institutions prepared to house BU animals temporarily if necessary until normal operations can resume
- Vendors available to replenish emergency supplies for animals as necessary
- Environmental Health & Safety

Training for the BSB's maintenance workers is provided annually by the animal facility supervisor and/or the Director of the BSB. Maintenance workers are escorted in the facility and not allowed in animal holding rooms when animals are present. Housekeeping is performed by animal facility personnel.

Each Laboratory has an emergency information posting outside the lab that includes emergency contact information, as well as hazard information for the lab. The Laboratory-Specific Documentation must include an emergency contact list for laboratory employees, including the Principal Investigator. The Laboratory Emergency Response Guide is posted near the exit and/or primary telephone for the lab.

Investigators are required to identify potential research hazards as part of the submission process. The committee requires investigators to identify hazards associated with each project and to provide the risk mitigation measures. This information is reviewed by the IACUC, EHS, and ORC at the time of submission review.

One-on-one training specific to the facility or an animal research use is provided by the facility director and/or the investigator. This training includes potential hazards (including symptoms of allergies), bites and scratches, and proper procedures to report and resolve issues. Facility directors and investigators are also responsible for training those working with the animals of the dangers and risks, including, but not limited to, discussions of zoonotic diseases, issues related to pregnancy, illness and immunocompetence. Documentation of training is available to the IACUC upon request and is made available during semiannual facility inspections.

All animal bites, scratches, or other injuries to an individual are to be reported to EHS, the animal worker's supervisor and/or the facility director. Individuals are directed to appropriate medical care. All facilities where animals are housed or where procedures with animals are performed must have appropriate signage regarding what to do in case of animal scratches, bites, or other injuries, who to contact, and access to first aid supplies. Records of all bites and scratches are kept in the "Bite/Scratch" logbook located in each animal care facility. In the event of illness or injury, students may receive treatment at Baylor University Health Services or may utilize local hospitals, clinics, or urgent care facilities. Personnel in need of emergency care, are instructed to dial 911 or the Baylor Police Department. For non-emergencies, faculty and staff utilize local hospitals, clinics, or urgent care facilities.

The university provides appropriate PPE based on hazard assessment. PPE provided includes, but is not limited to, eye and face protection, ear protection, gloves, respiratory protection, and appropriate clothing, head, and shoe coverings. Protective barrier suits are kept in



animal facilities and workers are provided with information on their use. Washing facilities and eyewash/shower stations are provided in animal facilities.

(Note: Non-human primates are not used in any animal facilities at Baylor University.)

- F. The total gross number of square feet in each animal facility (including each satellite facility), the species of animals housed there and the average daily inventory of animals, by species, in each facility is provided in the attached Facility and Species Inventory table.
- G. The training or instruction available to scientists, animal technicians, and other personnel involved in animal care, treatment, or use is as follows:

All students and faculty who work with animals, IACUC board members, and animal care staff are required to be familiar with federal laws, PHS policy, and university regulations regarding the care and use of animals, as well as basic principles of animal husbandry and use of animals in research and teaching. Training in these principles is required of all research personnel before the IACUC will approve an animal use protocol. Laboratory Safety and biohazards training for researchers is described in section E. Training may be acquired as described below.

#### Animal Care and Use Training Program

Before starting to work with live animals, faculty, students, staff and researchers at the institution are all required to complete an Animal Care and Use Training Program. This program is required for anyone submitting a protocol, animal care technicians, and other faculty and students who plan to use animals in research and/or teaching. For the program, the IACUC utilizes web-based training provided and administered by the Collaborative Institutional Training Initiative (CITI). CITI's Animal Care and Use materials cover the following topics: working with the IACUC and the veterinarian; federal regulations and policies; animal husbandry and housing; submitting an animal use protocol to the IACUC; alternatives to the use of animals; avoiding unnecessary duplication; pain and distress categories; surgery and post-surgical care; personnel training and experience; occupational health and safety; euthanasia; making changes to approved research; and reporting misuse, mistreatment, and non-compliance. Other modules are available for training on a specific species or procedure. Verification of successful completion of the web-based training is completed by ORC staff prior to releasing a submission for IACUC review. Additionally, principal investigators are responsible for ensuring that personnel receive appropriate training in animal care and procedures that are specific to his/her protocol.

#### Animal Care Technician Training

All animal care technicians are required to complete the Animal Care and Use Training Program noted above. In addition, the Director of each animal facility will give specialized instruction on specific responsibilities and animal husbandry required by the technician's job. The Director is responsible for ensuring that all employees receive proper instruction and remain familiar with animal care and use principles.


#### IACUC Board Member and Staff Training

All IACUC board members and staff are required to complete the web-based Animal Care and Use Training Program. Additionally, committee members and the Assistant Vice Provost for Research, Director of Compliance are provided with copies of the most current editions of the following: PHS Policy on Humane Care and Use of Laboratory Animals, Guide for the Care and Use of Laboratory Animals, Animal Welfare Act, Animal Welfare Regulations, and the IACUC Handbook, and web links to resources including PHS OLAW and USDA resources, along with institutional and committee policies and procedures. The current approved Animal Welfare Assurance, IACUC policies and procedures, and any other documentation relevant to the IACUC and to institutional animal care and use is available to all board members at a central, electronic location.

## **IV. 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 6 months and will be reevaluated by the IACUC at least once every 6 months according to PHS Policy IV.B.1.-2. Reports have been and will continue to be prepared according to 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 PHS Policy and 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 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.

## **V. Recordkeeping Requirements**

- A. This Institution will maintain for at least 3 years:
  - 1. A copy of this Assurance and any modifications made to it, as approved by the 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 granted or withheld
  - 4. Records of semiannual IACUC reports and recommendations (including minority views) as forwarded to the Institutional Official, Truell Hyde, PhD, Vice Provost for Research.
  - 5. Records of accrediting body determinations
- B. This Institution 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 3 years after completion of the activity.
- C. All records shall be accessible for inspection and copying by authorized OLAW or other PHS representatives at reasonable times and in a reasonable manner.

## **VI. Reporting Requirements**

- A. The Institutional reporting period is the calendar year (January 1 – December 31). The IACUC, through the Institutional Official, will submit an annual report to OLAW by January 31 of each year. The annual report will include:
  - 1. Any change in the accreditation status of the Institution (e.g., if the Institution obtains accreditation by AAALAC or AAALAC accreditation is revoked)
  - 2. Any change in the description of the Institution'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 the Institution's program and facilities (including satellite facilities) and submitted the evaluations to the Institutional Official, Truell W. Hyde, PhD, Vice Provost for Research.
  - 5. Any minority views filed by members of the IACUCIf there are no changes to report, the IACUC, through the Institutional Official, will provide written notification that there are no changes.
- B. The IACUC, through the Institutional Official, will promptly provide OLAW 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. and VI.B. above should include any minority views filed by members of the IACUC.



## VII. Institutional Endorsement and PHS Approval

<b>A. Authorized Institutional Official</b>	
Name: Kevin Chambliss, PhD	
Title: Interim Vice Provost for Research	
Name of Institution: Baylor University	
Address: (street, city, state, country, postal code) One Bear Place (b) (4) Waco, TX 76798-7310 USA	
Phone: (b) (6)	Fax: (b) (6)
E-mail: Kevin_Chambliss@baylor.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: 1/28/19

### B. PHS Approving Official (to be completed by OLAW)

Doreen H. Bartlett  
Senior Assurance Officer, Division of Assurances  
Office of Laboratory Animal Welfare (OLAW)  
National Institutes of Health  
6700B Rockledge Drive Suite 2500 MSC 6910  
Bethesda, MD 20892  
bartletd@od.nih.gov  
301-496-7163

Signature: Doreen H. Bartlett - S	Date: January 31, 2019
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Digitally signed by Doreen H.  
Bartlett - S  
Date: 2019.01.31 08:25:56 -05'00'

Assurance Number: D16-00538 (A3948-01)
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Effective Date: January 28, 2019
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Expiration Date: January 31, 2023
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# VIII. Membership of the IACUC

Date: 09/26/2018			
Name of Institution: Baylor University			
Assurance Number: A3948-01			
<b>IACUC Chairperson</b>			
Name*: N. Bradley Keele			
Title*: Professor of Psychology and Neurosciences		Degree/Credentials*: PhD	
Address*: (street, city, state, zip code) One Bear Place (b) (4) Waco, TX 76798-7334			
E-mail*: NB_Keele@baylor.edu			
Phone*: (b) (6)		Fax*: (b) (6)	
<b>IACUC Roster</b>			
Name of Member/ Code**	Degree/ Credentials	Position Title***	PHS Policy Membership Requirements****
(b) (6)			Scientist
			Scientist
N. Bradley Keele	PhD	Professor of Psychology and Neuroscience	Scientist
(b) (6)			Scientist
Ryan Stoffel	DVM, PhD, DACLAM	Veterinarian	Attending Veterinarian
(b) (6)			Non-affiliated
			Non-Scientist
			Scientist
			Ex-officio (non-voting)
			Ex-officio (non-voting)
			Ex-officio (non-voting)
			Ex-officio (non-voting)

\* This information is mandatory.



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

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

\*\*\*\* PHS Policy Membership Requirements:

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

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

## IX. Other Key Contacts (optional)

If there are other individuals within the Institution who may be contacted regarding this Assurance, please provide information below.

<b>Contact #1</b>	
(b) (6)	
<b>Contact #2</b>	
Name:	
Title:	
Phone:	E-mail:

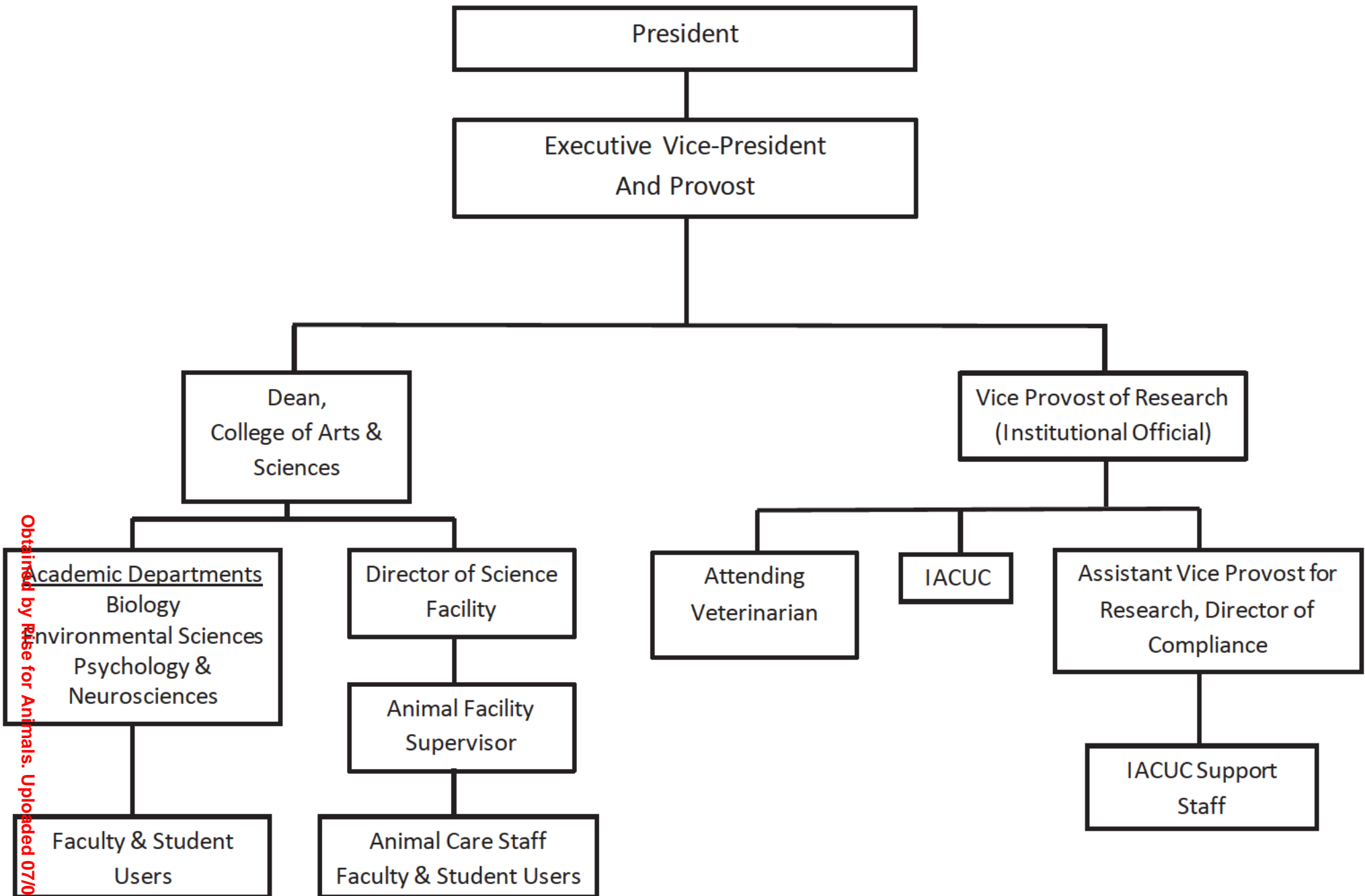


## X. Facility and Species Inventory

[illegible]

\*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.

## Current Lines of Authority and Responsibility







# BAYLOR UNIVERSITY

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE

MEMORANDUM

04/16/2018

TO: Trueell W. Hyde, PhD, Vice Provost for Research and Institutional Official  
File

FROM: Institutional Animal Care and Use Committee

RE: Semiannual Report of the Program Review and Facility Inspection

This report summarizes the IACUC's results of its most recent program review and facility inspection, as required by the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (Policy), Section IV B 1 -3 • the *Guide for the Care and Use of Laboratory Animals* (Guide), and the Animal Welfare Act (AWA) regulations, as applicable. Submission of semiannual reports to the Institutional Official is a condition of this institution's Animal Welfare Assurance with the NIH Office of Laboratory Animal Welfare (OLAW).

**Since the last review, the following changes have occurred in the institution's program for animal care and use (PHS Policy IV A 1 a -i):**

Addition of a Veterinary Verification and Consultation (WC) process.

**I. Description of the Nature and Extent of the Institution's Adherence to the PHS Policy, the Guide, and the AWA**

Departures from the PHS Policy, the *Guide*, and the AWA.

Select A or B:

- ☒ A. There were no departures during this reporting period.
- ☐ B. The following departures have been reviewed and approved by the IACUC:  
[include reason for each departure]

OFFICE OF THE VICE PROVOST FOR RESEARCH

One Bear Place #97310 • Waco, TX 76798-7310 • (254) 710-3763 • FAX (254) 710-7309

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## II. Deficiencies in the Institution's Animal Care and Use Program

Animal Care and Use Program Review Date(s):

Select A or B:

- ☐ A. There were no deficiencies in the program during this reporting period.
- ☒ B. The following deficiencies have been identified: *[describe each deficiency, identify each deficiency as either minor or significant, and provide a reasonable and specific plan and schedule for the correction of each deficiency, deficiencies may be recorded on a separate table and attached, the last page of OLAW's Sample Semiannual Program Review and Facility Inspection Checklist provides a sample table]*

Minor Deficiency: disaster planning and emergency preparedness. Current plans need to be updated. Review at next Semi-annual program review.

## III. Deficiencies in the Institution's Animal Facility

Animal Facility Inspection Date(s):

Select A or B:

- ☐ A. There were no deficiencies in the animal facility during this reporting period.
- ☒ B. The following deficiencies have been identified: *[describe each deficiency, identify each deficiency as either minor or significant, and provide a reasonable and specific plan and schedule for the correction of each deficiency, deficiencies may be recorded on a separate table and attached, the last page of OLAW's Sample Semiannual Program Review and Facility Inspection Checklist provides a sample table]*

Eight (8) minor deficiencies identified. See attachment #1.

## IV. Minority Views

Select A or B:

- ☒ A. No minority views were submitted or expressed.
- ☐ B. The following minority views were expressed: *[insert minority views here or attach]*



**V. Status of AAALAC Accreditation** *[identify accredited facilities, if applicable]*

Not accredited.

**VI. Signatures** *[signatures of a majority of the IACUC members required by AWAR (§2.31,c,3), if applicable]*

Names of IACUC Members	Signatures
Ryan Stoffel, DVM, PhD	(b) (6)
(b) (6)	
N. Bradley Keele, PhD	
(b) (6)	

# I BAYLOR UNIVERSITY

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE

## Attachment #1 to Semi-annual Report

The following deficiencies were identified:

Deficiency Category*	Location	Deficiency and Plan for Correction	Responsible Party	Date Completed
M	(b) (4)	Update "open date" on Tetra Min fish flakes. <b>Correction by next semi-annual inspection.</b>	(b) (6)	Check next inspection
M		Room air handling intake/return rusted. <b>Correction by next semi-annual inspection.</b>		Check next inspection
M		Cleaning of macroenvironment: dusting, rust, air filters dirty. <b>Correction by next semi-annual inspection.</b>		Check next inspection
M		Lighting above tanks needs proper install. <b>Correction by next semi-annual inspection.</b>		Check next inspection
M		Replace or seal unsealed wood structures in the fish housing area to facilitate cleaning and inhibit the growth of mold/mildew. <b>Correction by next semi-annual inspection.</b>		Check next inspection
M		Missing ceiling tiles (dirty side). <b>Correction by next semi-annual inspection.</b>	Ryan Stoffel	Check next inspection
M		Cleaning chemical barrel propped up to tilt (dirty side). <b>Correction by next semi-annual inspection.</b>	Ryan Stoffel	Check next inspection
M		Eye protection needed (dirty side). <b>Correction by next semi-annual inspection.</b>	Ryan Stoffel	Check next inspection

\*  
 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 IACUC and in annual report to OLAW)  
 Check if repeat deficiency

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