

**College of Charleston**  
A4376-01

**Animal Welfare Assurance for Domestic Institutions**

I, Frances Welch, as named Institutional Official for animal care and use at the College of Charleston, 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.

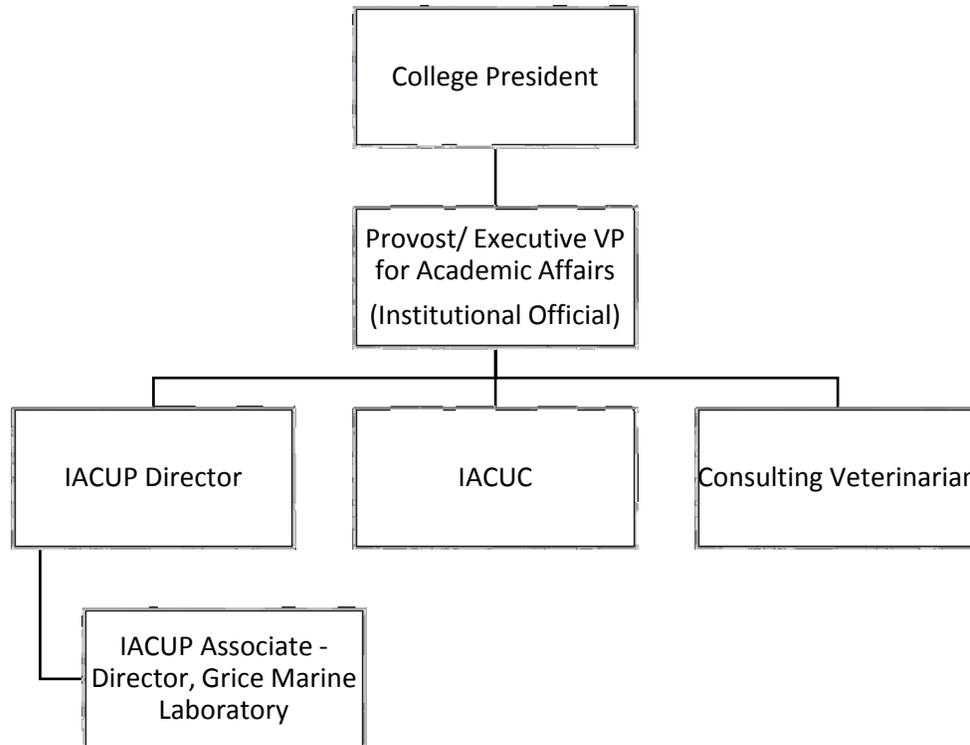
- A. The following are branches and components over which this Institution has legal authority, included are those that operate under a different name: College of Charleston main campus, Grice Marine Laboratory located approximately 15 minutes from the main campus, and Dixie Plantation, a field research site located approximately 45 minutes from the main campus. There are no other off-campus satellite facilities and / or other covered components.
- B. The following are other institution(s), or branches and components of another institution: None; not applicable.

**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 *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:



The Research Protections & Compliance Manager (RPC Manager) in the Office of Research & Grants Administration (ORGA), Division of Academic Affairs, provides administrative support to the IACUC and the IACUP.

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

1) Name: Doug Berger

Qualifications

- Degrees: D.V.M
- Training or experience in laboratory animal medicine or in the use of the species at the institution: Training or experience in laboratory animal medicine or in the use of the species at the institution: Dr. Berger is a member of the American Veterinary Medical Association (AVMA) and Trident Veterinary Medical Association. He graduated in 1988 from Ohio University with a B.S. in Zoology and was inducted into Phi Beta Kappa. Dr Berger is a 1992 graduate of the University of Tennessee College of Veterinary Medicine, where his training included laboratory animal medicine and exotics. He has attended IACUC 101 and IACUC 201 Plus training programs. He is in general private practice at All Creatures Veterinary Clinic in Charleston

Authority: Dr. Berger has direct program authority and responsibility for the Institution's animal care and use program including access to all animals. He has the authority to execute duties necessary to ensure adequate veterinary care of all vertebrate animals used in research and teaching at the Institution. These duties include, but are not limited to, reviewing protocols; reviewing and inspecting animal facilities and programs; assuring that programs are in place for the prevention, surveillance, diagnosis, and treatment of disease; reviewing the use of anesthetics, analgesics, tranquilizers, methods of euthanasia, and surgical and postoperative care; monitoring the well-being of animals with regard to proper animal husbandry, health, and freedom from pain and distress;

providing guidance to investigators and other personnel to ensure appropriate handling, immobilization, sedation, analgesia, anesthesia, and euthanasia; and guidance to surgery protocols. The Consulting Veterinarian is an ex officio voting member of the Institutional Animal Care and Use Committee (IACUC) and is engaged in the development of all policies and procedures related to the care and use of animals at the Institution. Dr. Berger is available for consultation and training of investigators, instructors, and staff on an as-needed basis.

Time contributed to program:

Dr. Berger is present at the Institution an average of approximately four (4) hours per month. All of this time is contributed to the animal care and use program or attending IACUC meetings. In addition Dr. Berger contributes on average approximately six (6) hours per month to the program while off-site reviewing protocols and providing consultation on various program related topics.

2) Name: Shane Boylan

Qualifications

- Degrees: D.V.M.
- Training or experience in laboratory animal medicine or in the use of the species at the institution: Dr. Boylan is a member of the Association of Zoos and Aquariums (AZA), American Association of Zoological Veterinarians (AAZV), Association of Reptile and Amphibian veterinarians (ARAV), International Association of Aquatic Animal Medicine (IAAAM), Turtle Survival Alliance (TSA). He is a licensed veterinarian South Carolina, North Carolina, and Missouri. He graduated in 1997 from the University of North Carolina Chapel Hill with a B.S. in Biology and minor in Chemistry, and is a 2005 graduate of North Carolina State College of Veterinary Medicine. Dr. Boylan has extensive experience with exotic and aquatic species. Prior to his current position as the first full time veterinarian for the South Carolina Aquarium and the South Carolina Sea Turtle Rehabilitation Program, Dr. Boylan was the sole staff veterinarian for the Dickerson Park Zoo. He holds adjunct faculty appointments at the College of Charleston and the Medical University of South Carolina.

Responsibilities:

Dr. Boylan is the primary veterinary reviewer for all protocols involving aquatic animals and provides training related to care and research utilizing aquatic species. In the absence of the Consulting Veterinarian or as delegated, the Alternate Consulting Veterinarian provides emergency veterinary care and assumes the responsibilities of the Consulting Veterinarian as needed

Time contributed to program:

Dr. Boylan is infrequently present at the Institution unless providing coverage during Dr. Berger's absence. In addition Dr. Boylan contributes on average approximately six (6) hours per month to the program while off-site reviewing protocols and providing consultation on various program related topics.

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:

- The IACUC will meet at least once every six months to review the Institutional Program for Humane Care and Use of Animals.
  - The Committee will use the Guide 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 will use a checklist based on the Sample OLAW Program and Facility Review Checklist from the OLAW website.
  - The evaluation will include, but not necessarily be limited to, a review of the following:
    - a. IACUC membership and functions,
    - b. IACUC records and reporting requirements,
    - c. Institutional and Individual Responsibilities
    - d. Husbandry and veterinary care (all aspects),
    - e. Personnel qualifications including experience and training,
    - f. Occupational health and safety,
    - g. Security (personnel and facility),
    - h. Disaster planning, and
    - i. 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.
  - Subcommittees may be used to conduct all or part of the reviews. However, no member will be involuntarily excluded from participating in any portion of the reviews.
- 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:
- At least once every six months at least two voting members of the IACUC will visit all of the institute's facilities where animals are housed or used, i.e., holding areas, animal care support areas, storage areas, procedure areas, surgery areas, and laboratories where animal manipulations are conducted. Equipment used for transporting of the animals is also inspected.
  - The Committee will use the *Guide* 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 will use a checklist based on the Sample OLAW Program and Facility Review Checklist from the OLAW website.
  - 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.
  - Subcommittees may be used to conduct all or part of the inspections. However, no member will be involuntarily excluded from participating in any portion of the inspections.
  - For individual facilities that house or involve only non-USDA covered species, the Institutional Animal Care and Use Committee (IACUC) may, at its discretion, determine the best means of conducting an evaluation of the institution's programs and facilities. The IACUC may invite ad hoc consultants to assist in conducting the evaluation. However, the IACUC remains responsible for the evaluation and report.

- 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:
- Individual IACUC members will convey their observations to the IACUC Chairperson, or his or her designee, who, in turn, will draft the reports using the sample OLAW Semiannual Report to the Institutional Official format from the OLAW website.
  - The reports will contain a description of the nature and extent of the institution's adherence to the Guide and the PHS Policy.
  - The reports will identify specifically any IACUC approved departures from the provisions of the Guide and the PHS Policy, and state the reasons for each departure. If there are no departures the reports will so state.
  - Approved departures must be approved as part of a protocol, protocol amendment, or other written document, using either FCR or DMR as delineated below in Section III.D.6.
  - Departures from the provisions of the Guide that are not IACUC approved are considered deficiencies and addressed as such in the report.
  - The reports will distinguish significant deficiencies from minor deficiencies. If program or facility deficiencies are noted, the reports will contain a reasonable and specific plan and schedule for correcting each deficiency.
  - If some or all of the institution's facilities are accredited by AAALAC International the reports will identify those facilities as such.
  - Copies of the draft reports will be reviewed, revised as appropriate, and approved by the Committee.
  - The final reports will be signed by a majority of the IACUC members and will include any minority opinions. If there are no minority opinions, the reports will so state.
  - Following completion of each evaluation, the completed report will be submitted to the Institutional Official in a timely manner—generally within 60 days of the evaluation.
  - After the semiannual review meeting, the Chair, IACUC Director, or RPC Manager, as designated, will notify the individuals identified in the correction plan of the action required.
  - Should significant protocol-related deficiencies be found that immediately and seriously jeopardize the health and safety of the animals, the IACUC may, as necessary, suspend the protocol and assign full responsibility for care of the animals to the IACUC Director. Such decision will require a majority vote of a convened quorum of members, in-person or via real time video or telecommunications. The Protocol PI shall be contacted immediately about alternative housing or other action as deemed necessary.
  - Corrections of minor deficiencies are reported to the IACUC at a convened meeting and documented in the minutes. Correction of significant deficiencies is reported immediately to the IO.
  - The IO and Committee will track all noted deficiencies to ensure that they are appropriately resolved.
- 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, Institutional Veterinarian, or any member of the IACUC.
  - Concerns may be reported either orally or in writing.
  - 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. These notices are also posted on the Institution's IACUC webpage.
  - 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, in writing, to the IO and, as warranted, to OLAW. Reports to the IO may be either via meeting minutes, semiannual report of IACUC evaluations, or separate letter. Reports to OLAW will be in writing and through the IO. Preliminary reports to both the IO and OLAW may be made verbally.
- 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) 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:
- The Animal Care and Use Protocol Review Form (ACUPRA) is PDF form is submitted via email by the Principal Investigator (PI) to the RPC Manager.
  - The RPC Manager pre-reviews the application for completeness, returning it to the PI if necessary.
  - When a completed ACUPRA is received, the RPC Manager posts it on the IACUC secure website and an e-mail notification is sent to all IACUC members that the protocol is available for review.
  - IACUC review is accomplished through the mechanisms of Designated Member Review (DMR) or Full Committee Review (FCR). The USDA pain and distress categories are used to determine the method of review: Generally, DMR for categories B and C, FCR for categories D and E.
  - For FCR, the ACUPRA should be received by the RPC Manager at least two weeks prior to a scheduled IACUC meeting. Review of the protocol will be accomplished at a convened meeting at which a majority of the members (or their alternates) are present.
  - In time sensitive situations, expedited review of a protocol requiring FCR may be requested by a PI by notifying the IACUC at the time of posting of the request for review. The IACUC Chair may call a special IACUC meeting, with a convened quorum of members

or via real time video or telecommunication, specifically for the purpose of review of the protocol.

- For DMR, the ACUPRA may be submitted to the RPC Manager at any time to be posted for review.
- In time sensitive situations, expedited review of a protocol qualifying for DMR may be requested by a PI by notifying the IACUC at the time of posting of the request for expedited review. The RVPC Manager will coordinate the review time table, assuring that all members have adequate time to request FCR.
- Meetings are generally conducted in person, but may occasionally be conducted by teleconference or videoconference. Any use of telecommunications will be in accordance with NIH Notice NOT-OD-06-052 of March 24<sup>th</sup>, 2006, entitled *Guidance on Use of Telecommunications for IACUC Meetings under the PHS Policy on Humane Care and Use of Laboratory Animals*.
- Meetings are conducted in accordance with general parliamentary procedure, but not strict adherence to Robert's Rules of Order.
- A quorum is required for the conduct of business. At no time will more than three serving individuals be from the same administrative unit, e.g. academic department.
- Members vote orally. Guests or persons with a conflict of interest are required to leave the meeting during voting.
- Prior to the review, each IACUC member will be provided access via the IACUC's secure website to written descriptions of activities (protocols) that involve the care and use of animals and any member of the IACUC may obtain, upon request, full committee review (FCR) of those protocols.
- If FCR is requested, approval of those protocols 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.
- The possible outcomes of FCR are as follows:
  - a. approval,
  - b. require modifications (to secure approval), and
  - c. withhold approval.
- If FCR is not requested, at least one member of the IACUC, designated by the chairperson and qualified to conduct the review, may be assigned to review those protocols and have the authority to:
  - a. approve,
  - b. require modifications in (to secure approval), or
  - c. request FCR of those protocols.
- Other IACUC members may provide the designated reviewer with comments and/or suggestions for the reviewer's consideration only. That is, concurrence to use the designated-member review (DMR) method may not be conditioned.
- When multiple designated reviewers are used and additional modifications are required, the final protocol will be posted on the secure IACUC members website for review.
- If multiple designated reviewers are used, their decisions must be unanimous; if not, the protocol will be referred for FCR. Designated reviewers will review identical versions of the protocol and if modifications are requested by any one of the reviewers then the other reviewers must be aware of and agree to the modifications.

- Generally, the DMR method will be used for protocols assigned to USDA categories B and C, and FCR is used for USDA categories D and E. When using DMR, 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 three (3) working days, and approval of protocols via DMR are maintained and recorded in the minutes of the next convened IACUC meeting.
- Required modifications subsequent to FCR. When the IACUC requires modifications (to secure approval), of a protocol, such modifications are reviewed as follows:
  - a. FCR or DMR following the procedures delineated above;  
OR
  - b. DMR following FCR is currently practiced in accordance to institutional procedures, "DMR Following FCR Standard Operating Procedures." These procedures require that:
    - a. the entire current Committee has previously approved, in advance and in writing, 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. DMR following FCR permission forms are distributed for signature at the first IACUC meeting of each academic year and original, signed paper copies are stored in the Office of Research and Grants Administration.
    - b. DMR is approved unanimously by all members at the meeting at which the required modifications are developed delineated
 However, any member of the IACUC may, at any time, request to see the revised protocol and/or request FCR of the protocol.

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 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.
- 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.
- In order to approve proposed protocols or proposed significant changes in ongoing protocols, the IACUC 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. Further, 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 American Veterinary Medical Association (AVMA) Guidelines for the Euthanasia of Animals, unless a deviation is justified for scientific reasons in writing by the investigator.
- 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:
- Request for all changes to an approved protocol must be submitted on the approved IACUC modification form and are posted for review on the IACUC secure website.
  - Significant changes must be approved by one of the valid IACUC approval methods described in the PHS Policy IV.C.2., FCR or DMR.
  - Examples of changes considered to be major (significant) include, but are not necessarily limited to changes:
    - a. in the objectives or scope of an approved animal activity (*NIH Grants Policy Statement Part 2 8.1.2.5.*);
    - b. from non-survival to survival surgery;
    - c. that have the potential to increase the level of pain or distress of the animal;
    - d. in housing and or use of animals in a location that is not part of the animal program overseen by the IACUC;
    - e. in animal species;
    - f. in Principal Investigator;
    - g. that impact personnel safety;
    - h. in anesthesia, analgesia, or sedation;
    - i. in the method of euthanasia;
    - j. in the duration, frequency, interval, type, number, or anatomical location of procedures performed on an animal and in substances delivered to the animal;
    - k. change in animal numbers\*
 

\*changes of less than 10% in the approximate number of mice of the genus *Mus* and rats of the genus *Rattus* that are purposely bred for use in research may, at the IACUC's discretion, be considered not significant
  - Changes that are not significant may be handled by the IACUC Chair or IACUC staff without IACUC review and approval). However, the IACUC is to be informed of changes handled by the IACUC staff. This information may be provided after the change has been reviewed and initiated. Examples of changes considered to be minor (not significant) may include, but are not limited to:
    - a. change in personnel other than the Principal Investigator (An appropriate administrative review must be conducted to ensure that all such personnel are appropriately identified, adequately trained and qualified, enrolled in applicable occupational health and safety programs, and meet other criteria as required by the IACUC. The IACUC should have a procedure in place to ensure that this review is conducted.);

- b. change that would result in less discomfort or invasiveness to the animal, except the changes described in section A.;
  - c. change in stock, strain, or genetic modification, unless the new stock, strain, or modification results in abnormalities that require special support;
  - d. change in the sex of the animals;
  - e. change in the vendor;
  - f. change in the route of administration of a compound (if there is no increase in pain or distress);
  - g. addition of some minor non-invasive procedures;
  - h. correction of typographical errors;
  - i. correction of grammar; or
  - j. updates of contact information.
- 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:
- Principal Investigators are notified either by e-mail or letter from the RPC Manager as directed by the IACUC chair.
  - If the IACUC's decision is to require modifications to secure approval, the required modifications are delineated in the written notification.
  - If the IACUC decides to withhold approval, it will include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing. The IACUC Chair may appoint one or two IACUC members to work with the investigator. The IACUC will consider the investigator's response at a convened meeting, and may invite a revised protocol for further review. The final decision of the IACUC may not be overruled by an institutional official.
  - The Institutional Official is notified by receiving 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 at least once every 3 years according to PHS Policy IV.C.1.-5. The IACUC procedures for conducting continuing reviews are as follows:
- Post Approval Monitoring – The Institution does not have a formal PAM program. Due to the small size of the animal research program, communication is frequent among IACUC members, Animal Care and Use personnel, and researchers. Protocols are monitored in a number of ways including semi-annual inspections and annual review of protocols. In-facility daily research activities are monitored by the Institutional Animal Care and Use Program (IACUP) Director and Associate IACUP Director for GML. Additional review may be directed by the IACUC based on risk determination or reported problems. Review components may include (but are not limited to):
    - a. Comparison of animal usage numbers to date with approved numbers in the protocol;
    - b. Inquiry about any observed, unexpected deaths or other adverse events;
    - c. Review of protocol records;
    - d. Inspection of animal use and study areas;
    - e. Procedure observations.
  - A continuing review form should be submitted to the RPC Manager by the PI no less than 30 days prior to the end of year 1 and year 2 of the approved protocol. A more frequent review schedule may be determined at the time of protocol review if deemed necessary.

- The continuing review form is posted for review on the IACUC secure website with the protocol file.
- Continuing review includes, but is not necessarily limited to the following: a report of animals used in the previous year and any reportable events, as well as projected animal numbers and housing requirements, if any, for the upcoming year. The continuing review may also include review of any modifications projected for the next year.
- USDA Covered Species – Protocols involving USDA covered species are reviewed by a voting member or members of the IACUC at least every 12 months using either FCR or DMR as described in Part III.D.6. above.
- Non-USDA Covered Species – Protocols involving only non-USDA covered species are submitted as de novo every three years and reviewed by a member or members of the IACUC using either FCR or DMR as described in Part III.D.6. above.
- Protocols are approved for a maximum of 36 months. That is, all protocols expire no later than the three-year anniversary of the initial IACUC review.
- If activities will continue beyond the expiration date, prior to expiration of the original or preceding protocol a new protocol must be submitted, reviewed, and approved as described in Paragraph III.D.6. above.
- Submitted and approved annual protocol reviews are available to all IACUC members on the secure website and are reported to the IACUC at the next convened meeting.
- Annual protocol reviews are recorded in the IACUC meeting minutes.
- The IACUC meeting minutes are reviewed and approved by the Committee.

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:

- 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, in writing, to OLAW. Initial/preliminary reports may be made telephonically.

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:

#### **1. Administration/Management.**

- The Environmental Health and Safety Director will be responsible for the overall management of the Occupational Health and Safety (OHS) Program for personnel involved in the care and/or use of laboratory animals.
- An Occupational Health Professional / Specialist is involved in planning and monitoring the program.

## **2. Scope.**

- The OHS Program covers all personnel, including students, involved in animal care and/or use.
- Prior to beginning work with live animals, employees will be contacted by RPC to enroll in the OHS. Individuals may decline to participate in the health program. However the Institution may restrict their participation to activities that pose no identifiable occupational health-related risks as determined by a health professional

## **3. Hazard Identification and Risk Assessment.**

- The program is based on hazard identification and risk assessment.
- Potential hazards are identified by the Principal Investigator for the research or by the Animal Care and Use Director in consultation with the Consulting Veterinarian and/or Occupational Health and Safety professional if needed.
- A risk assessment form which includes a description of relevant job responsibilities will be completed by the Principal Investigator and each person listed on the protocol.

## **4. Health Histories and Evaluations.**

- The risk assessment form along with a brief health history form will be taken by the employee to either the Institution's Student Health Services or contracted Occupational Health Provider (for which there will be no charge) or by the employee's personal physician (at the employee's expense). Evaluation will be performed by a health care professional.
- Non-employed students listed as research personnel on an animal protocol will complete and take the Risk Assessment and health history forms to the Institution's Student Health Service for evaluation.
- Clearance or clearance with restrictions will be communicated by the evaluator to RPC who will notify the IACUP Director and the employee or student's research supervisor for follow-up.
- Immunizations required as a result of the health evaluation will be made available through the Institution's contracted Occupational Health Provider or the Institution's Student Health Service at no cost. Immunizations through a private health care provider will be at the employee or student's expense. Certification of immunization will be submitted to the RCP, Director of the IACUP, and the employee or student's research supervisor prior to any contact with live animals.
- Confidentiality and other medical and legal factors will be considered in the context of appropriate federal, state, and local regulations.

## **5. Common Identified Hazards and Risks.**

- The most common hazards and risks include, but are not limited to the following:
  - a. physical hazards, e.g. syringes, needles, or other sharps;
  - b. animal handling, e.g., bites or scratches;
  - c. chemical hazards, e.g., spills;
  - d. biologic agent hazards;
  - e. allergies;
  - f. handling of waste materials;

- g. cage washer use;
  - h. zoonoses; or
  - i. field hazards, terrestrial and aquatic, identified by the PI.
- The IACUC's Animal Care and Use Protocol Review Application requires research investigators and teaching faculty using animals to identify any reasonably foreseeable protocol-specific health or safety risks and to describe the training that personnel will require.

## **6. Procedures in Place to Alleviate Hazards and Minimize Risks.**

- Components of the program to alleviate hazards and minimize risks will be as follows:
  - a. Training for all personnel involved in animal care and use. Training will include:
    - hazard identification and risk assessment;
    - facilities, procedures, and monitoring;
    - applicable safety issues including zoonoses, chemical safety, physical hazards, allergies (including early identification and reporting of symptoms), handling of waste materials, precautions during pregnancy, illness or immune suppression;
    - issues specific to the research protocol and animal handling;
    - personal hygiene and the use of personal protective equipment;
    - procedures in event of an injury; and
    - emergency procedures.
  - b. Appropriate personal protective equipment (PPE).
  - c. Appropriate safety equipment, including eyewash stations.
  - d. Standard Operating Procedures.
  - e. Ongoing assessment of hazards and risks.
- If, during the protocol review, the IACUC has concerns about health and safety of personnel involved in an animal protocol that are not adequately addressed, the IACUC will, prior to approving the protocol, consult with the campus Environmental Health and Safety Director and will determine, on a case-by-case basis, what additional protections and/or surveillance should be required.
- The PI is tasked with assuring that all personnel (including students for teaching protocols) involved in a protocol receive the training, and the IACUP Director is tasked with assuring that IACUP staff receive the training.
- Multiple resources are available to the PI to assure comprehensive training, including consultation with the IACUP director, the Institutional Environmental Health and Safety director, consulting veterinarians, and departmental laboratory supervisors.

## **7. Immunizations.**

- Current tetanus vaccination will be required, unless waived for medical reasons. Other immunizations will be required or made available as necessary for work with specific animals.

## **8. Precautions taken during pregnancy, illness or decreased immunocompetence.**

- All personnel involved in animal care and use will receive training by the PI or the IACUP Director regarding precautions that should be taken during personal pregnancy, illness or decreased immunocompetence.

## **9. Provisions for personnel who are not involved in animal care and/or use but nevertheless need to enter areas when animals are housed or used.**

- Personnel who are not involved in animal care and/or use but nevertheless need to enter areas when animals are housed or used (e.g., building maintenance, security,

housekeeping) will receive instruction as appropriate from the IACUP Director or Grice Co-Director before entering those areas.

**10. Availability and procedures for treatment in the event of bites, scratches, illness or injury.**

- In event of bites, scratches, illness, or injury (including exposure to potentially hazardous animal fluids) while working with animals in the College's animal facilities or classroom, personnel are required to contact College of Charleston Department of Public Safety and follow instructions given by Public Safety dispatcher/responders.
- In the event of injury in the field, personnel should report to the nearest hospital emergency room for treatment.
- The incident must be reported to the IACUP Director or Grice Co-Director; the supervisor, PI, or faculty advisor; and, if an employee, the Office of Human Resources. Report will then be submitted to the Environmental Health and Safety Director.

**11. Procedures/program for reporting and tracking injuries and illnesses.**

- Each administrative unit or academic department is required to keep records of bite wounds, other injuries, and/or unusual illnesses experienced by employees or students who participate in animal activity. These records must be available to the IACUC upon request. Any significant problems noted by the administrative unit or academic department must be reported in writing to the IACUC and Institutional Official.
- 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:
- 1. Overview.** The Institutional Animal Care and Use Manual, links to regulatory agencies, training resources, online training programs, and guidance regarding specific species and ethical issues, and are available on the ORGA IACUC and Responsible Conduct of Research webpages. Workshops on specific topics may be provided as needed. CITI Program training is available to all personnel and IACUC members covering regulatory and species specific issues, with tracks defined for IACUC members, researchers, and some laboratory classes as requested by the instructors.
  - 2. IACUC Members**
    - Each IACUC member will be provided with a current copy (in either print or electronic format access as preferred) of the following:
      - a. The PHS Policy for the Humane Care and Use of Laboratory Animals,
      - b. The National Research Council (NRC) Guide for the Care and Use of Laboratory Animals,
      - c. The ARENA/OLAW IACUC Guidebook,
      - d. The current AVMA Guidelines on Euthanasia, and
      - e. A copy of this Assurance.
    - All IACUC members are required to complete the IACUC members track of the CITI Program every three (3) years.
    - New IACUC members complete an orientation session with the RPC Manager in addition to CITI Program training. Topics covered include introduction to the regulations,

resources on the OLAW website, important issues and resources, expectations of an IACUC member, and how to use the ORGA IACUC webpage for general information and the IACUC secure website to access and review protocols.

- All IACUC members will be provided with OLAW updates, e.g., OLAW FAQs, Policies and Laws, Guidance, Educational and other Resources, at least semi-annually by the RPC Manager, the IACUC Chair, or the IACUP Director. IACUC members are encouraged to visit the OLAW website.
- ORGA provides funding for the IACUC Chair to attend an IACUC 101, IACUC 102, IACUC Advanced, PRIM&R/ARENA IACUC meeting or other topic based training when appropriate.
- The RPC Manager must complete the CITI Program training modules specific to IACUC functions and the tutorials for PHS policy on the OLAW website every three (3) years. ORGA provides funding for attendance at relevant conferences and workshops.
- Consulting Veterinarians receive ongoing training through attendance at workshops and meetings as appropriate. ORGA provides funding for the Consulting Veterinarians to attend IACUC 101 and IACUC 201 Plus or other relevant conferences

### **3. Animal Care and Use Personnel.**

- A copy of this Assurance will be sent to all persons involved in animal care and use and will be posted on the IACUC members website. A copy will be available in the animal care facilities.
- Training for researchers is provided on an individual need-specific basis by the IACUP director, the Consulting Veterinarians, or through online programs. Topics covered may include, but are not limited to, methods that minimize the number of animal required to obtain valid results, statistical procedures to calculate optimal number of animals, new methods to minimize pain and distress, refreshers on humane practice of animal care and use, or specific training in new equipment or techniques.
- Research personnel maintain up-to-date knowledge through journals and attendance at professional conferences and meetings.
- New researchers receive orientation to animal facilities and procedures by the IACUP director and are directed specifically to the ORGA IACUC webpage resources.
- Students working with animals in research projects or classroom activities receive comprehensive training in animal handling and safety by their instructors (protocol PIs). In many cases, the research students have already completed a research methodology course.
- Training for the IACUP Director in animal care and husbandry is accomplished by attendance at workshops and meetings, and consultation with colleagues at other animal care programs, including the Medical University of South Carolina (located less than a mile from the College.)
- The IACUP Director provides animal husbandry training to facility animal care employees. Training covers basic issues related to the daily care of the animals and facility and focuses on health and maintenance issues.
- All personnel 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 available for IACUC review.

- Any person needing additional protocol-specific training will be identified during the review process and such required training must be completed prior to performing the specified protocol related work involving animals.
- All persons involved in animal care and use will be required to attend an orientation seminar given by the IACUC Chair, Consulting Veterinarian, or other qualified individual(s), which covers the laws and regulations covering laboratory animal care and use with an emphasis on the contents of the NRC Guide and the 3R's.
- 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, as applicable, training and instruction of personnel must include guidance in at least the following areas:
  - a. Humane methods of animal maintenance and experimentation, including:
    - the basic needs of each species of animal,
    - proper handling and care for the various species of animals used by the facility,
    - proper pre-procedural and post-procedural care of animals, and
    - aseptic surgical methods and procedures.
  - b. The concept, availability, and use of research or testing methods that limit the use of animals or minimize animal distress.
  - c. Proper use of anesthetics, analgesics, and tranquilizers for any species of animals used by the facility.
  - d. 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.
  - e. Utilization of services (e.g., National Agricultural Library, National Library of Medicine) available to provide information:
    - On appropriate methods of animal care and use,
    - On alternatives to the use of live animals in research,
    - That could prevent unintended and unnecessary duplication of research involving animals, and
    - 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.
- 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.
- 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.

## **2. IACUC Members**

- Each IACUC member will be provided with a current copy (in either print or electronic format access as preferred) of the following:
  - f. The PHS Policy for the Humane Care and Use of Laboratory Animals,
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  - h. The ARENA/OLAW IACUC Guidebook,
  - i. The current AVMA Guidelines on Euthanasia, and
  - j. A copy of this Assurance.
- All IACUC members are required to complete the IACUC members track of the CITI Program every three (3) years.
- New IACUC members complete an orientation session with the RPC Manager in addition to CITI Program training. Topics covered include introduction to the regulations, resources on the OLAW website, important issues and resources, expectations of an IACUC member, and how to use the ORGA IACUC webpage for general information and the IACUC secure website to access and review protocols.
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- ORGA provides funding for the IACUC Chair to attend an IACUC 101, IACUC 102, IACUC Advanced, PRIM&R/ARENA IACUC meeting or other topic based training when appropriate.
- The RPC Manager must complete the CITI Program training modules specific to IACUC functions and the tutorials for PHS policy on the OLAW website every three (3) years. ORGA provides funding for attendance at relevant conferences and workshops.
- Consulting Veterinarians receive ongoing training through attendance at workshops and meetings as appropriate. ORGA provides funding for the Consulting Veterinarians to attend IACUC 101 and IACUC 201 Plus or other relevant conferences

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- Research personnel maintain up-to-date knowledge through journals and attendance at professional conferences and meetings.
- New researchers receive orientation to animal facilities and procedures by the IACUC director and are directed specifically to the ORGA IACUC webpage resources.
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- All personnel 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 available for IACUC review.
- Any person needing additional protocol-specific training will be identified during the review process and such required training must be completed prior to performing the specified protocol related work involving animals.
- All persons involved in animal care and use will be required to attend an orientation seminar given by the IACUC Chair, Consulting Veterinarian, or other qualified individual(s), which covers the laws and regulations covering laboratory animal care and use with an emphasis on the contents of the NRC Guide and the 3R's.
- 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, as applicable, training and instruction of personnel must include guidance in at least the following areas:
  - f. Humane methods of animal maintenance and experimentation, including:
    - the basic needs of each species of animal,
    - proper handling and care for the various species of animals used by the facility,
    - proper pre-procedural and post-procedural care of animals, and
    - aseptic surgical methods and procedures.
  - g. The concept, availability, and use of research or testing methods that limit the use of animals or minimize animal distress.
  - h. Proper use of anesthetics, analgesics, and tranquilizers for any species of animals used by the facility.
  - i. 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.
  - j. Utilization of services (e.g., National Agricultural Library, National Library of Medicine) available to provide information:
    - On appropriate methods of animal care and use,
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- 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.

#### **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, Frances Welch.
  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 government fiscal year (October 1 – September 30). The IACUC, through the Institutional Official, Frances Welch, will submit an annual report to OLAW by December 1 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, Frances Welch
  - 5. Any minority views filed by members of the IACUC
  
- 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: Frances Welch, Ph.D.	
Title: Interim Provost and Executive Vice President of Academic Affairs	
Name of Institution: College of Charleston	
Address: 66 George St, Charleston, SC 29424	
Phone: 843-953-5613	Fax: 843-953-5840
E-mail: <a href="mailto:welchf@cofc.edu">welchf@cofc.edu</a>	
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: 	Date: 4/15/2020

<b>B. PHS Approving Official</b> <i>(to be completed by OLAW)</i>	
<p>Name/Title: Paula Knapp, Animal Welfare Policy Scientist Office of Laboratory Animal Welfare (OLAW) National Institutes of Health 6700B Rockledge Drive Suite 2500, MSC 6910 Bethesda, MD 20892-6910 Phone: +1 (301) 496-7163 Fax: +1 (301) 451-5672</p>	
Signature:  <b>Knapp -S</b>	Date: April 16, 2020
Assurance Number: D16-00689 (A4376-01)	
Effective Date: April 16, 2020	Expiration Date: March 31, 2024

## VIII. Membership of the IACUC

Date: 1/7/2020			
Name of Institution: College of Charleston			
Assurance Number: A4376--01			
<b>IACUC Chairperson</b>			
Name: John Widholm			
Title: Professor of Psychology			Degree/Credentials*: Ph.D.
Address: Department of Psychology College of Charleston 66 George Street Charleston, SC. 29412			
E-mail: widholmj@cofc.edu			
Phone: 843-953-8194			Fax: 843-953-7151
<b>IACUC Roster</b>			
Name of Member/ Code**	Degree/ Credentials	Position Title***	PHS Policy Membership Requirements****
Doug Berger	D.V.M.	Veterinarian, Private Practice	Consulting Veterinarian
U2	M.S.	Marine Environmental Specimen Bank Biologist <sup>1</sup> (NIST) /Community Member	Unaffiliated
NS10	Ph.D.	Professor, Philosophy Dept.	Non-scientist
S32	Ph.D.	Professor, Biology Dept.	Scientist
S5	Ph.D.	Assoc. Professor, Psychology Dept.	Scientist
S25	Ph.D.	Assoc. Professor, Biology Dept.	Scientist
S26	Ph.D.	Assoc. Professor, Biology Dept.	Scientist
S31	Ph.D.	Assoc. Professor, Psychology Dept.	Scientist
Shane Boylan	D.V.M.	Veterinarian, S.C. Aquarium	Alternate - Consulting Veterinarian
AltS9	Ph.D.	Assoc. Professor, Biology Dept.	Alternate - Scientist S25, S26, & S31
AltS32	Ph.D.	Assoc. Professor, Psychology Dept.	Alternate - Scientist S5, S26, & S32
105	M.P.A	Research Protections & Compliance Mgr.	Non-voting - ex officio
102	Ph.D.	IACUP Director, Assoc. Professor, Psychology Dept.	Non-voting - ex officio
103	B.S.	Assoc. IACUP Director, Marine Mgr., Grice Marine Lab.	Non-voting - ex officio

104	M.S.	Environmental Health & Safety Director, staff	Non-voting – ex officio

1- No interaction with living animals

**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>	
Name: Sara Stevenson, MPA	
Title: Research Protections & Compliance Manager	
Phone: 843-323-2372	E-mail: stevensonsm1@cofc.edu or compliance@cofc.edu
<b>Contact #2</b>	
Name: Garrett Milliken, Ph.D.	
Title: Institutional Animal Care and Use Program Director; Associate Professor of Psychology	
Phone: 843-953-5443	E-mail: millikeng@cofc.edu

**X. Facility and Species Inventory**

Date: 10/25/2019			
Name of Institution: College of Charleston			
Assurance Number: A4376-01			
Laboratory, Unit, or Building*	Gross Square Feet [include service areas]	Species Housed [ <i>use common names, e.g., mouse, rat, rhesus, baboon, zebrafish, African clawed frog</i> ]	Approximate Average Daily Inventory
MC1	10,800 sf	Rat Mouse Pigeon	47 31 15
MC2	360 sf	Frogs	10
GML	850 sf	Blenny Plane Head Filefish Spade Fish Northern Puffer Striped Burrfish Diamondback Terrapin Florida Pompano Clown fish Triple Tail Red Eared Slider Yellow Tang Fire Fish	1 1 6 1 4 3 2 3 1 1 1 1