



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:

Office of Laboratory Animal Welfare
Division of Assurances
6705 Rockledge Drive
RKL 1, Suite 360, MSC 7982
Bethesda, Maryland 20892-7982
Home Page: <http://grants.nih.gov/grants/olaw/olaw.htm>

FOR EXPRESS MAIL:

Office of Laboratory Animal Welfare
Division of Assurances
6705 Rockledge Drive, Suite 360
Bethesda, Maryland 20817
Telephone: (301) 496-7163
Facsimile: (301) 451-5672

March 3, 2015

Reference: Assurance **A4514-01**

Dr. Karen Ryan
Dean of the College of Arts and Sciences
Stetson University
421 North Woodland Boulevard
DeLand, Florida 32723

Dear Dr. Ryan:

Thank you for your correspondence of February 26, 2015

It is my pleasure to inform you that your institution's PHS Animal Welfare Assurance (Assurance number A3444-01) is approved.

As you know, your institution's Assurance was conditionally approved on August 26, 2014. The approval was conditioned on the receipt of specified information and/or materials.

OLAW received, reviewed, and accepted the requested items. Your institution's Assurance is now unconditionally approved. The approval and expiration dates remain unchanged – **August 26, 2014 and August 31, 2018**, respectively.

The Assurance is a key document in defining the relationship of your Institution to the PHS. It sets forth the responsibilities and procedures of your Institution regarding the care and use of laboratory animals. Among the important elements of the Assurance are the reporting requirements that are essential for continued compliance with the PHS Policy. Please note that a Report to OLAW is required at least once every 12 months. The reporting period, unless requested otherwise in writing, is the calendar year. Reports, for the previous calendar year, are due **January 31**.

If we may be of further assistance, please do not hesitate to contact me or Dr. Parlett.

Thank you for your attention to these matters.

Sincerely,

Eileen M. Morgan
Director, Division of Assurances
Office of Laboratory Animal Welfare, NIH

Enclosure

cc:
Dr. David Stock

STETSON UNIVERSITY
D16-00726
ANIMAL WELFARE ASSURANCE

I, Dr. Karen Ryan, as named Institutional Official for animal care and use at Stetson 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. This Assurance covers only those facilities and components listed below.

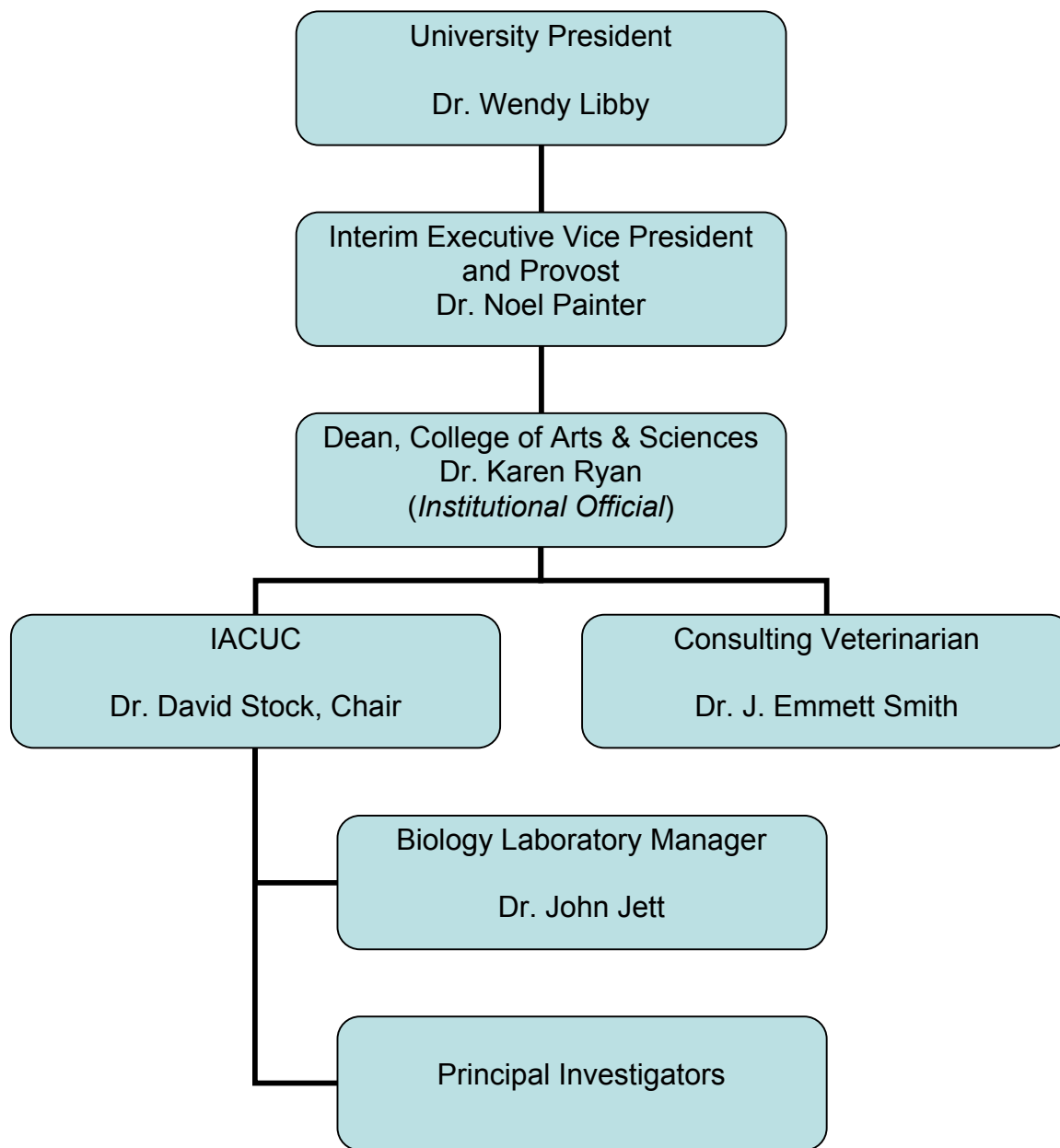
- A. The following are branches and components over which this Institution has legal authority, included are those that operate under a different name: All Stetson University components (Colleges, Schools, Centers, Departments, etc.) that are physically located on the University's DeLand campus at Woodland Blvd in DeLand, Florida. No off-campus satellite facilities and/or other components are covered in this Assurance.
- B. No other institution(s), or branches and components of another institution are covered by this Assurance.

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 (sub-award) 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 as follows:



As indicated above, there are direct and open lines of communications between the IACUC and the Institutional Official (IO) and between the Veterinarian and the IO.

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

1. Name: J. Emmett Smith

Qualifications:

- Degrees: D. V. M., Auburn University, 1964
- Training or experience in laboratory animal medicine or in the use of the species at the institution: Dr. Smith obtained laboratory animal training from the University of Auburn College of Veterinary Medicine. In addition he worked in the Army Veterinary Corps, two years, working with large animals mainly horses and mules, in private veterinary practice in DeLand, Florida, 49 years, working with dogs and cats.

Authority: Dr. J. Emmett Smith has delegated program authority and responsibility for The Institution's animal care and use program including access to all animals.

Time contributed to program: Dr. Smith, a veterinarian in DeLand is present at the Institution an average of approximately one hour per month. One-hundred percent of this time is contributed to the animal care and use program. In addition Dr. Smith contributes on average approximately one hour per month to the program while off-site reviewing protocols and providing consultation on various program related topics.

2. Provisions for Back-up Emergency Veterinary Care:

Name: Dr. Erin Holder

Qualifications:

- Degrees: BS Stetson University
DVM University of Florida College of Veterinary Medicine
CVA Chi Institute
- Training or experience in laboratory animal medicine or in the use of the species at the institution: Dr. Holder obtained laboratory animal training from the University of Florida College of Veterinary Medicine. Dr. Holder is experienced also in wildlife rehabilitation.

Responsibilities: Provide back-up veterinary care at times Dr. Smith is unavailable

Time contributed to program: As needed for back-up veterinary services

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 President, as Chief Executive Officer (C.E.O.) has delegated to the Institutional Official the authority to appoint members of the IACUC. In accordance with the Health Research Extension Act of 1985, this delegation of authority is specific and is in writing. The IACUC

consists of at least five members, and its membership meets the composition requirements of PHS Policy IV.A.3.b. Part VIII 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 six months the Institution's program for humane care and use of animals, using the Guide as a basis for evaluation. The IACUC procedures for conducting semiannual program reviews are as follows:

- The IACUC will meet at least once every six months to review the Institutional Program for Humane Care and Use of Animals.
- The Committee uses 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 Checklist from OLAW website.
- The evaluation will include, but necessarily be limited to, a review of the following:
 - a. IACUC Membership and Functions;
 - b. IACUC Records and Reporting Requirements;
 - c. Husbandry and Veterinary Care (all aspects);
 - d. Personnel Qualifications (Experience and Training);
 - e. Occupational Health and Safety; and
 - f. Review of the Emergency and Disaster Plans

In addition, the evaluation will include a review of the Institution's PHS Assurance.

- If program deficiencies are noted during the review, they will be categorized as significant or minor and the Committee will develop a reasonable and specific plan and schedule for correcting each deficiency. A significant deficiency is one that is or may be a threat to the health and safety of the animals or personnel.
- No member will be involuntarily excluded from participating in any portion of the reviews.

2. Inspect at least once every six 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 members of the IACUC will visit all of the Institution's facilities where animals are housed or used, i.e. holding areas, animal care support areas, storage areas, animal surgery areas, procedure areas,

and laboratories where animal manipulations are conducted. Equipment used for transporting of the animals is inspected also.

- The Committee uses 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.
- No member will be involuntarily excluded from participating in any portion of the inspection.

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 PHS Policy, 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 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. The IACUC will develop a reasonable plan and schedule for discontinuing the departure or for having the departure properly reviewed and approved.
- The reports will distinguish significant deficiencies from minor deficiencies. If the program of facility deficiencies is 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 report 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 include any minority opinions. If there are no minority opinions, the reports will reflect such.
- Following completion of each evaluation, the completed report will be submitted to the IO in a timely manner.
- Deficiencies will be tracked by the IACUC Chair to ensure that they are resolved appropriately.

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.
- 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. In addition one may learn of the instructions for reporting animal welfare concerns on the IACUC webpages. These instructions are identical to posted instructions.
- 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 document. 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 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:

- Protocols are submitted electronically to the IACUC Chair who acknowledges their receipt electronically.
- The IACUC Chair previews the protocols and accepts them as is for distribution to the IACUC as a whole or returns them to the authors with suggestions for improvement before submission to the IACUC Chair to distribute to the IACUC as a whole.
- IACUC members receive an electronic copy of every protocol as submitted by the author.
- Protocols are distributed to IACUC members electronically one week in advance of the meeting when those protocols will be discussed.
- All meetings are conducted in person.
- No member may participate in the IACUC review or approval of a protocol in which the member has a conflicting interest (i.e. is personally involved in the project) except to provide information requested by the IACUC; nor may a member who has conflicting interest contribute to the constitution of 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.
- Any use of telecommunications will be in accordance with NIH Notice NOT-OD-06-052 of March 24th, 2006, entitled Guidance on Use of Telecommunications for IACUC Meetings under PHS Policy on Humane Care and Use of Laboratory Animals.
- Prior to the review, each IACUC member will be provided with written descriptions of the protocol activities (protocols) that involve the care and use of animals and any member of the IACUC may obtain, upon request, full committee review of these protocols.

Full-Committee Review (FCR)

- 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 of a majority of the quorum present.
- The IACUC votes by show of hands or voice vote.
- Three outcomes can arise from the FCR: 1) approval, 2) require modifications

to secure approval, or 3) approval withheld (rejection of proposal - either outright and/or in its present form).

- Review of 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 in the PHS Policy and elsewhere in Part III.d.6 of this Assurance.

OR

- b. DMR if approved unanimously by all members at the meeting at which the required modifications are developed/delineated AND if all IACUC members have previously agreed in writing (e.g., documented a policy) that the quorum of members present at a convened meeting may decide by unanimous decision to use DMR subsequent to FCR when modification is needed to secure approval. 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 administrative nature, i.e., typographical or grammatical errors, required signatures, etc., may be confirmed by IACUC administrative/support personnel.

Designated-Member Review (DMR)

- Generally, the FCR method will be used. However, should a situation warrant it, the institution or IACUC may want to use the designated-member review (DMR) method. In such instances, the protocol will be distributed to all IACUC members to allow all members the opportunity to call for FCR; records of polling of members to obtain concurrence to use the DMR method, or concurrence by silent assent after five working days, and approval of protocols via DMR are maintained and recorded in the minutes of the next convened IACUC meeting.

- If full-committee review (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 approve, require modifications in (to secure approval), or request full committee review 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 DMR method may not be conditioned.

- After all required modifications are made, electronic copies of the final revised protocol are submitted to all designated reviewers for review and approval.

- If multiple designated reviewers are used, their decisions must be unanimous; if

not, the protocol will be referred for FCR.

- The DMR reviewers can 1) approve, 2) require modifications to secure approval, or 3) request FCR.
- There are no alternate processes or procedures for special or expedited reviews.
- In order to approve proposed protocols or proposed significant changes in ongoing protocols, the IACUC will conduct a review by FCR or DMR 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 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 killed painlessly 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 and studied.
 - e. Medical care for animals will be available and provided as necessary by a qualified veterinarian.
 - f. Personnel conducting procedures on the species being maintained or studied will be appropriately qualified and trained in those procedures.
 - g. Methods of euthanasia used will be consistent with the current recommendations of the American Veterinary Medical Association (AVMA) Guidelines on Euthanasia, unless a deviation is justified for scientific reasons in writing by the investigator.

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:

- Review and approval of significant changes are handled in the same manner as new protocols. See Paragraph III.D.6 above.
- Examples of changes considered to be significant include, but are not limited to:
 - α. in the objectives of the study;
 - β. from non-survival to survival surgery;
 - χ. resulting in greater discomfort or in greater degree of invasiveness;
 - δ. in the species or in the approximate number of animals used;
 - ε. in Principal Investigator;
 - φ. in anesthetic agent(s) or the use or withholding of analgesics;
 - γ. in the method of euthanasia; and
 - η. in the duration, frequency, or number of procedures performed on an animal.

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:

- Principle Investigators are notified either by email or letter from the IACUC Chairperson.
- If the IACUC's decision is to require modifications to secure approval, the Principal Investigators will be notified electronically what the required modifications are.
- As noted before, in cases where approval is withheld, the Principal Investigators will be notified of what the IACUC found unacceptable and how the protocol might be modified to make the protocol acceptable. The PI may respond to the IACUC in person and/or in writing to the IACUC Chair.
- The Institutional Official is notified by receiving a copy of the PI's notification letter and/or a copy of the IACUC meeting minutes.

9. Conduct continuing review of each previously approved, ongoing activity covered by PHS Policy at appropriate intervals as determined by the IACUC, including a complete review at least once every three years according to PHS Policy IV.C.1.-5. The IACUC procedures for conducting continuing reviews are as follows:

- Post-approval Monitoring - All ongoing activities are monitored continuously by the animal care and use staff. The IACUC conducts post-approval monitoring by

examining the Continuing Reviews PIs must submit semiannually to see that the agreed upon proposals are being followed. There are no further procedures for post-approval monitoring.

- USDA Regulated Species – Protocols involving USDA regulated species are reviewed by a member or members on the IACUC at least annually.
- Non- USDA Regulated Species – IAW institutional policy, continuing review of protocols involving only non-USDA regulated species, is handled using the same procedures as for USDA regulated species.
- Animal protocol reviews are recorded in the IACUC meeting minutes. The IACUC meeting minutes are reviewed and approved by the Committee.
- 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, a new protocol must be submitted, reviewed, and approved [prior to expiration of the original or preceding protocol] as described in Paragraph III.D.6. above.

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. Preliminary reports may be made verbally.
- If the IACUC Chair or Veterinarian find or believe that a situation is an immediate threat to the health or well-being of an animal(s), or the safety of personnel, he or she has the authority to suspend immediately such activity. Such suspensions will be reported promptly to the full IACUC for further review and disposition.

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 IACUC is responsible for the overall management (development, implementation, monitoring, etc.) of the Occupational Health and Safety Program for personnel involved in the care and/or use of laboratory animals.

2. Scope.

- Covered personnel include faculty, staff, students and individuals whose job responsibilities require them to provide program or support services within animal facilities (maintenance, housekeeping staff, and IACUC members). Visiting faculty, staff, students or researchers who have vertebrate animal contact must provide proof of current participation in a similar program at their host institution.
- Investigators are responsible for ensuring that all persons working under the scope of their protocol(s) complete the training offered by the IACUC regarding zoonosis, allergies, hazardous materials, pregnancy, immune suppression and other medical conditions that might put a worker at risk. Investigators are responsible for ensuring that all persons working under the scope of their protocol(s) comply with the provisions of the Occupational Health and Safety Program. Individuals are not permitted to work with animals until certification has been completed.
- The principal investigator is identified on protocols and significant change forms submitted to the IACUC. Approval of protocols, significant changes and biennial submissions are placed into a 'Requires Modifications' status until all individuals have completed certification.
- The occupational health requirements are determined by the level of risk associated with each animal species, extent of animal handling, pre-existing conditions and use of hazardous agents. All individuals as identified above are required to complete certification.
- All individuals are required to re-enroll at least once every two years and are advised to update their status at any time their circumstances change (i.e., change in health status), addition of new species to the protocol, hazardous procedures are added to protocol or there are increases in animal contact.
- Following risk assessment, enrollees are provided with recommendations from the contract occupational health physician for further action (vaccinations, physical exams, additional personal protective equipment, etc.). Enrollees may choose to accept or decline any or all of the recommendations unless such is mandated by the occupational health physician or required as a condition for performing specific research activities. A copy of the recommendations is provided to the enrollee as well as the Institutional Officer. The Institutional Officer may choose to share the

recommendations with the IACUC during discussion of specific protocols or significant changes if a concern is raised. If an enrollee declines specific recommendations and if the Institutional Officer, the IACUC or the occupational health physician deem recommendations to be a requirement, individuals may be removed from a protocol or a particular activity with animals.

- The Institutional Officer maintains the database of personnel enrolled and notifies individuals when biennial enrollment is due. The Institutional Officer also notifies the IACUC Chair of the dates individuals initially enroll, dates of re-enrollment and failure to enroll or re-enroll.
- Individuals failing to enroll or re-enroll are not permitted to work with animals and the IACUC may choose to temporarily remove an individual or suspend a protocol for failure to participate.
- Individuals declining additional evaluations, tests, vaccinations or procedures may choose to re-enroll at any time and will be re-evaluated by the contract occupational health physician at that time.

3. Health Histories and Evaluations.

- Individuals provide health history relevant to their use of animals on the program's enrollment form. They are asked to discuss any pre-existing or health related concerns with the occupational health physician during the risk assessment or follow-up process.
- Evaluation of individualized risk for occupational health and safety is performed by a contract occupational health physician; follow-up exams, tests and other procedures may be performed by either the contract occupational health physician or the individual's medical provider (enrollee's choice).

4. Hazard Identification and Risk Assessment.

- The program is based on hazard identification and risk assessment.
- The questionnaire completed by an individual for enrollment is used to determine what hazards may be involved. Hazards will be identified by the occupational health physician and the risk assessment completed and returned to the individual. Hazards are also identified during protocol review by the IACUC or a veterinarian.
- Risk assessment may be performed during the Occupational Health and Safety Program enrollment and evaluation by the occupational health physician or during protocol review by the IACUC or by a veterinarian. When deemed necessary a risk assessment by a specialty consultant is requested. Typically hazards include items of biological, chemical, or physical in nature. (Stetson University has no facilities for X radiation and radioisotopes.) During protocol review either the IACUC or a veterinarian may request modifications prior to approval. If, during the review,

additional items are determined to be hazardous, they are added to the risk assessment.

- To identify additional hazards, the IACUC performs independent inspections semiannually of all laboratories, animal housing, and procedural areas.
- The IACUC monitors adherence to established policies and standard operating procedures during the semiannual inspections or during post-approval monitoring visits (if hazards are in use at the time). All animal facility users and other university employees accessing animal facilities are encouraged to immediately report or correct any unsafe or potentially unsafe working condition.

5. Procedures in Place to Alleviate Hazards and Minimize Risks.

- Training: Training is provided regarding zoonosis, allergies, hazardous materials, pregnancy, immune suppression and other medical conditions that might put a worker at risk. This is done through a combination of people (including the occupational health physician and the principal investigator) and specialized educational materials. Individual laboratory training is available upon request or required in the case of unusual or particularly dangerous agents. Training must be completed before individuals may work with a hazardous agent.
- Personal Hygiene requirements include:
 - a. No eating, drinking, smoking, gum chewing, applying cosmetics or handling contact lenses where animals are housed.
 - b. Protective clothing shall be worn in animal areas and removed prior to leaving those areas.
 - c. Hand washing is required after handling animals and prior to leaving an animal housing area.
 - d. All work surfaces are required to be decontaminated daily after each procedure.
- PPE requirements are determined by the IACUC and the occupational health physician. This is done on a case-by-case basis and is determined by the potential hazard. PPE includes clothing, hearing protection, respiratory protection, eye protection, etc. Protocols requiring special protective equipment must have the requirements posted on the animal room door.

6. Immunizations.

- The institution follows the immunization recommendations of the occupational health physician. Tetanus vaccinations are highly recommended. Immunizations, if recommended by the occupational health physician, are covered under the Occupational Health and Safety Program.

7. Precautions taken during pregnancy, illness or decreased immunocompetence.

- Individuals with special conditions (illness, immunosuppressed, pregnancy, etc.) are encouraged to discuss their work with animals/in animal facilities with their

personal physician or to update their information with the occupational health physician. Recommendations from either a personal physician or the occupational health physician are discussed and implemented on a case-by-case basis to the extent possible for reasonable accommodation.

8. 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.

- The Occupational Health and Safety Program covers personnel not involved in animal care and/or use. Supervisors are routinely reminded to identify such personnel for enrollment in the program and evaluation by the occupational health physician.
- In situations where outside (non-university) maintenance personnel, contractors, or visitors access the animal rooms, they are briefed on appropriate precautions and provided any appropriate PPE and are then permitted in for a limited amount of time. A member of the animal care staff will be available for escort if needed. If there is extensive or prolonged work to be done the animals are removed prior to the individuals being allowed into the room.
- Housekeeping and maintenance staff are not routinely allowed to access the animal facilities.

9. Availability and procedures for treatment of bites, scratches, illness or injury.

- Signs are posted in all facilities, providing guidance to injured individuals for steps to be taken for medical assessment and treatment in case of accidents, injuries and animal bites or scratches. The signs include information about emergency health facility locations and phone numbers and describe steps for non-emergency animal bite first aid.
- In the event of a severe injury or emergency, 911 and Public Safety (if on campus) are called to respond and provide immediate care for the individual. If injury occurs to an employee, including work-study students or interns during the course of their duties, he or she will be covered fully under the institution's Workers Compensation insurance and medical providers including any emergency treatment needed. Risk Management is notified and an accident report is completed and submitted so that the appropriate workers compensation reporting, authorization, and claims process may be implemented. If injury occurs to a student, he or she has access to the institution's on-site Student Health Services. If required, emergency treatment is also available at Florida Hospital, DeLand, which is 1.3 miles from the institution.
- For non-severe injuries, employees are to notify a supervisor to seek medical treatment. If the condition requires treatment beyond in-house first aid, the supervisor will contact Risk Management so that an accident form can be submitted and medical treatment can be arranged for the individual with an approved Workers Compensation medical provider and the appropriate claims

filing will be implemented. If a non-severe injury occurs to a student, he or she has access to the institution's on-site Student Health Services.

10. Procedures/program for reporting and tracking injuries and illnesses.

- Upon first notice of a work-related injury or illness, the department in which the incident occurred, along with the employee, initiates and completes an Employee Accident Report and submits it to Risk Management. Risk Management submits a Workers Compensation claim and obtains authorized medical treatment for the employee with a Workers Compensation provider for any medical treatment that is needed. All work-related injuries are tracked by Risk Management by hard copy and an injury tracking software program. They are also recorded by the Workers Compensation insurance company and by the Florida Department of Labor Workers Compensation Division. Once a report has been submitted, a loss control follow up is conducted in conjunction with the Biology Lab Manager, the principal investigator, and Risk Management in order to implement any loss control needed to prevent similar injuries or illnesses in the future.
- If a (non-employee) student is injured or becomes ill from working with animals, the principal investigator completes a Student Health Services Accident Report and submits it to Student Health Services. Student Health Services obtains medical treatment for the student, including any emergency treatment or ER/ambulance care that is needed. Animal-related injuries or illnesses are tracked by Student Health Services by hard copy and the types of laboratory animal-related injuries or illnesses are reported to the IACUC in order to implement any loss control needed to prevent similar injuries or illnesses in the future.

11. Other Pertinent Information Regarding the OH&S Program.

- Special standard operating procedures are in place for individuals working with venomous snakes. These are detailed in Stetson University's agreement with the Florida Wildlife Commission.
- There are no non-human primates at Stetson 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 animal, by species, in each facility is provided in Part X., the 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. **IACUC Training**

- Each IACUC member will be provided with a copy 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 AVMA Guidelines on Euthanasia;
 - e. A copy of this Assurance.
- All members of the IACUC will complete the Essentials for IACUC Members Curriculum located at the American Association for Laboratory Animal Science website, www.aalaslearninglibrary.org or the Collaborative Institutional Training Initiative website, www.citiprogram.org.
 - All IACUC members will visit the OLAW website at least semiannually and will complete the IACUC tutorial module (initial visit) and will familiarize themselves with the other pertinent modules and information, e.g. OLAW FAQs, Policies and Laws, Guidance, Educational, and other Resources.
 - Attendance at an IACUC 101, IACUC 102, IACUC Advanced, PRIM&R/Arena IACUC meeting, or similar course may be substituted for any IACUC training session.

2. Animal Care and Use Personnel

- During the Training Program of the IACUC participants are introduced to Stetson's Assurance and told it is available on the IACUC webpage. Also a hardcopy is placed in the IACUC reserve in the Stetson Library.
- 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 will be a condition of approval for the protocol.
- 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 or instruction on research or testing should include 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:
 1. Humane methods of animal maintenance and experimentation, including:
 - a. The basic needs of each species of animal;

- b. Proper handling and care for the various species of animals used by the facility;
- c. Proper pre-procedural and post-procedural care of animals, and
- d. Aseptic surgical methods and procedures.

2. The concept, availability, and use of research or testing methods that limit the use of animals or minimize animal distress.

3. Proper use of anesthetics, analgesics, and tranquilizers for any species of animals used by the facility.

4. Methods whereby deficiencies in animal care and treatment are reported, including deficiencies in animal care and treatment reported by any employee of the facility. No facility employee, Committee member, or laboratory personnel shall be discriminated against or subject to any reprisal for reporting violations of any regulation or standard under the Act.

5. Utilization of services (e.g. National Agricultural Library, National Library of Medicine) available to provide information:

- a. On appropriate methods of animal care and use;
- b. On alternatives to the use of live animals in research;
- c. that could prevent unintended and unnecessary duplication of research involving animals; and
- d. Regarding the intent and requirements of the Animal Welfare Act and USDA-APHIS Regulations.

- On-line training may be used and accepted in lieu of 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 similar training, verification of previous training in lieu of the Institution's training is solely at the IACUC's discretion.

IV. Institutional Program Evaluation and Accreditation

- A. All of this Institution's programs and facilities (including satellite facilities) for activities involving animals have been evaluated by the IACUC within the past six months and will be reevaluated by the IACUC at least once every six 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.

- B. 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 three 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, Dr. Karen Ryan, Dean of the College of Arts and Sciences.
 - 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 three 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, Dr. Karen Ryan, Dean of the College of Arts and Sciences.
 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
- B. 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

A. Authorized Institutional Official	
Name: Dr. Karen Ryan	
Title: Dean of the College of Arts and Sciences	
Name of Institution: Stetson University	
Address: <i>(street, city, state, country, postal code)</i> 421 North Woodland Blvd. DeLand, Florida USA 32723	
Phone: 386-822-7515	Fax: 386-822-7514
E-mail: karen.ryan@stetson.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:	Date:

B. PHS Approving Official <i>(to be completed by OLAW)</i>	
Name/Title: Office of Laboratory Animal Welfare (OLAW) National Institutes of Health 6705 Rockledge Drive RKL1, Suite 360, MSC 7982 Bethesda, MD USA 20892-7982 (FedEx Zip Code 20817) Phone: +1 (301) 496-7163 Fax: +1 (301) 915-9465	
Signature:	Date:
Assurance Number:	
Effective Date:	Expiration Date:

VIII. Membership of the IACUC

Date: May 1, 2014			
Name of Institution: Stetson University			
Assurance Number: D16-00726			
IACUC Chairperson			
Name*: David Stock			
Title*: Professor of Biology			Degree/Credentials*: Ph.D.
Address*: (street, city, state, zip code)			
421 North Woodland Blvd. Unit 8285 DeLand, Florida 32723			
E-mail*: *: dstock@stetson.edu			
Phone*: 386-822-8174		Fax*: 386-822-8179	
IACUC Roster			
Name of Member/ Code**	Degree/ Credentials	Position Title***	PHS Policy Membership Requirements****
David Stock	Ph.D.	Professor-Biology	Scientist
J. Emmett Smith	D.V.M.	Veterinarian	Veterinarian
Member C	Ph.D.	Professor-English	Nonscientist
Member D	Ph.D.	Assistant Professor- Psychology	Nonscientist
Member E	Ph.D.	Professor – Biology	Scientist
Member F	B.A.	Lineman for power company (retired)	Non-affiliated Member
Member G	B.A.	Office assistant (retired)	Non-affiliated Member

* 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:

<i>Veterinarian</i>	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.
<i>Scientist</i>	practicing scientist experienced in research involving animals.
<i>Nonscientist</i>	member whose primary concerns are in a nonscientific area (e.g., ethicist, lawyer, member of the clergy).
<i>Nonaffiliated</i>	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.

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.

Contact #1	
Name: Dr. Diane Everett	
Title: Professor of Sociology and Associate Dean of the College of Arts and Sciences	
Phone: 386-822-7244	E-mail: ddeveret@stetson.edu
Contact #2	
Name:	
Title:	
Phone:	E-mail:

X. Facility and Species Inventory

[illegible]

Unless otherwise indicated, mice and rats means mice of the genus mus and rats of the genus rattus that are purposely bred for research.

Memorandum to: Karen Ryan, PhD., Dean of College of Arts and Sciences and Institutional Officer for Stetson University Animal Welfare Assurance

From: Institutional Animal Care and Use Committee

Subject: Semiannual Report of the Program Review and Facility Inspection

Date: May 1, 2014

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.](#)): [optional]

No changes have occurred in the Institution's program for animal care and use.

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]*

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]*

--

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]*

There were no departures from the <i>Guide, 8th Ed.</i> , PHS Policy, and/or USDA regulations.

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]*

No facilities at Stetson University are accredited by AAALAC.

Semiannual Report of IACUC

Signatures

Date: May 1, 2014

Names of IACUC Members	Signatures
Ron Hall	Ron Hall
Melissa Gibbs	Melissa Gibbs
Renate Calero	Renate Calero
J. EMMETT SMITH	J. Emmett Smith
David Stock	David Stock