CHAPMAN UNIVERSITY | INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE

Continuing Review and Annual Report Form

Date: version: 8 Oct 2018

Principal Investigator Name:

Department/College:

Co-PI(s):

IACUC Protocol Number:

Protocol Study Title:

Approval date:

Previously approved species:

Previously approved locations:

Previous housing exceptions:

Animal use annual review (v7)

The IACUC has determined that it will perform annual reviews as part of its oversight of the Chapman animal care and use program. It applies to research, teaching, and testing protocols. It comprises part of the PAM (post-approval monitoring) process. It utilizes this regulatory verbiage from the AWAR, which says "The IACUC shall *conduct continuing reviews* of activities covered by this subchapter at appropriate intervals as determined by the IACUC, but not less than annually." The annual review is sometimes also known as a continuing review or status report, which occurs at the end of *years one and two* of the typical three-year approval period for an IACUC-approved protocol. It is not the same as an agency progress report, though both have some of the same components.

Importantly, the annual review also serves as a point in the protocol cycle to reflect on and update the IACUC about concerns pertaining to the approved uses of animals. Changes may require an amendment to be filed. Examples of information related to an amendment include: new personnel not yet added to the protocol, deletion of personnel, other training achieved, changes in procedures, increasing animal numbers, changes to animal welfare, and more.

Annual reviews are due **by** the dates of the first and second years after the original protocol approval date, but not sooner than 30 days ahead.

Begin by indicating for which year of the protocol cycle this review applies.

- ◯ year 1
- ◯ year 2

Continuing the protocol?

- ◯ Yes, I want to continue the animal work associated with this protocol.
- ◯ No, continuation of this protocol is no longer necessary, because it was never used.
- ◯ No, the use covered by this protocol has been completed.

Continuation - justification

Write a few sentences as to why you as the PI want to continue with this protocol. This is to satisfy regulatory and funder expectations. Provide a brief progress report of work completed during the past year on achieving the specific aims of the protocol.

Examples of information to include: need to finish an experiment, a summary of what has been completed, an indication of what is planned in the coming year and remaining period of the protocol, how many animals have been used so far, any difficulties in completing the experiments, continuing a teaching course.

Not continuing the protocol - animal use has been completed

- ◯ As the PI, I will complete a "closure" form for this protocol.
- ◯ I ask that the IACUC office administratively close this protocol on my behalf.

Have any adverse events occurred?

If **Yes**, please provide details below and in the form (Animal Concern Reporting, or Adverse Event Report, Form) to be provided by the IACUC. (The IACUC reviews adverse event reports during its meetings.)

An adverse event is the occurrence of an unforeseen event that negatively impacts the welfare of animal(s) used in research or teaching, involving pain, distress, and/or death of the animal. By definition, adverse events are not pre-identified as potential risks or outcomes in the approved IACUC protocol.

Record of animal usage: How many animals were used?

How many animals were used during the last year (reporting period)? Provide a number as accurate as possible. Describe strain, gender, etc. as it pertains to the protocol and study objectives.

Species	Animal use classification "C," "D," or "E"	Total # requested	Total # used since last annual review

Did any animals experience a welfare issue, e.g., pain and/or distress, not originally described in the protocol?

Will an amendment for an increase in animal numbers be submitted?

- ◯ yes
- ◯ no
- ◯ not sure

Were there any personnel changes?

If additions, have they been included in the protocol through an amendment, including training and RASQ? If deletions, please note them here.

Does the funding agency or other entity require a letter...?

...for continuation or completion or other circumstance? A standard closure memo will be written and archived. If the research team needs something else, please contact the IACUC office.

- ◯ yes
- ◯ no

Explanatory notes regarding the annual review

Provide any other information related to the annual review.

Principal Investigator Assurance

As Principal Investigator, I acknowledge that I have ultimate responsibility of the performance of this study, the ethical and humane care and use of the animals, and strict adherence by all study team members to IACUC requirements, all federal, state and local laws, and the regulations and policies of Chapman University governing the use of animals in research, teaching and testing. To that aim, I agree to abide, as applicable, by the ILAR Guide for the Care and Use of Laboratory Animals (2011), the USDA Animal Welfare Regulations (CFR 1985) and Public Health Service Policy on Humane Care and Use of Laboratory Animals (1996), and other usage guidelines (and with their updates).

On behalf of my team, I hereby assure the following:

1. The information provided in this application is accurate to the best of my knowledge.

2. I have performed the required "alternatives to animals" searches and to the best of my knowledge, the experiments and procedures described in this protocol do not unnecessarily duplicate previous experiments, unnecessarily use animals, or unjustifiably expose animals to potentially painful, uncomfortable or distressful procedures.

3. All experiments and procedures involving animals will be performed under my supervision or that of another qualified professional listed on this protocol.

4. I will ensure that all study team members are informed, qualified, and authorized to conduct procedures involving animals under this protocol. This includes ensuring that all study team members, including myself, have:
   - Been (or will be) trained in handling and care of the involved species and approved procedures in this protocol, including the proper use of anesthetics, analgesics, experimental agents, and euthanasia.
   - Enrolled in Chapman's occupational health and safety program (RASQ and LAOHP).
   - Completed the CITI Training on animal care and use and other required vivarium training courses (as applicable).
   - Read and understand the procedures outlined in the approved protocol.

5. Personnel will be allowed adequate time to obtain necessary training for this project and will not begin any procedures with live animals until they have been successfully trained.

6. All animal acquisition will be coordinated through the vivarium and all animals will be housed in the vivarium, unless otherwise approved by the IACUC as described here in the protocol.

7. Emergency veterinary care is permitted for animals showing evidence of pain or illness not addressed specifically in the approved protocol, in addition to routine veterinary care as prescribed for individual species. In the event that animals in this study experience pain or distress that cannot be adequately relieved, I will euthanize those animals immediately based on recommendations of the vivarium veterinary staff or IACUC

8. All study team members with direct animal contact are registered in the Chapman University Laboratory Animal Occupational Health Program. All study team members are aware of the potential hazards associated with the use of live animals and animal tissues. In addition, I understand I am responsible for notifying Chapman's Risk Management/EH&S if an individual's level of animal contact changes, due to changes in the protocol or job description.

9. I understand that, should I use the project described in this application as a basis for a proposal for funding (either intramural or extramural), it is my responsibility to assure that the description of animal use in the funding proposal(s) is identical in principle to that contained in this application. I will submit changes as amendments/modifications to the IACUC as necessary to assure that these are identical.

10. I and all of the co-investigators and research personnel agree to comply with all applicable requirements for the use of animal in research, testing and teaching at Chapman including, but not limited to, the following:
    - Performing any changes to the approved protocol without first having submitted those changes for review and approval by the IACUC;
    - Promptly responding to and providing the IACUC with any information requested relative to the project during inspections and programmatic reviews;
    - Promptly and completely complying with an IACUC decision to suspend or withdraw its approval for the project;
    - Obtaining continuing review prior to the date approval for when this study expires. Additionally, I understand that if I fail to apply for continuing review, approval for the study will automatically expire, and study activity must cease until a *de novo* protocol application is reviewed and approved;
    - Filing a final report with the Chapman IACUC at the conclusion of this project.

As the PI of this animal use protocol, yes, I agree and provide my assurance to the statements above.

Printed name of PI

Signature of PI (digital signature acceptable)

Members of the Research Team
Provide the names of all persons engaged with the animals on the study.