TITLE: Request for Change to Approved Animal Numbers (USDA)

PURPOSE: All IACUC SOP numbered 5xx describe the specific incidences where a protocol can be modified using the Request for Change procedure outlined in IACUC SOP 500.

To request a change in approved animal numbers.

REVIEW/REVISIONS: The IACUC will review and approve this SOP every six months. Modifications may be made at any time by full committee review (FCR) or designated member review (DMR). Updates to internet URLs or Unit names can occur without FCR/DMR.

DATE OF LAST REVIEW: 05/03/2018

PROCEDURES:

If the Request for Change meets the criteria below, it is eligible for veterinary consult and verification, by the process outlined in IACUC SOP 500.

- Excludes non-human primates
- Limits on animal numbers are for the protocol approval period and are not cumulative
- There is no change to approved animal activities
  - Larger USDA-regulated species:
    - Replacement of animals lost as a result of reported adverse events
    - No more than the number of animals listed in a reported adverse event, up to 5% of the number originally approved within that pain category
  - USDA-regulated rodents:
    - Replacement of animals lost as a result of reported adverse events
    - No more than the number of animals listed in a reported adverse event
    - Additional animals to address an insufficient group size
    - Additional test compound of the same class (IACUC SOP 512)
    - Additional group for post-mortem activities
    - No more than 10% of the number originally approved within that pain category

JUSTIFICATION:

NOT-OD-14-126 Guidance on Significant Changes to Animal Activities describes the types of animal activities where the IACUC has the authority to establish and approve internal policies/procedures for the review and approval of protocol amendments.

USDA agreement with NOT-OD-14-126: http://grants.nih.gov/grants/olaw/educational_resources.htm#a_08212014