TITLE: Request for Change to Approved Surgical Procedures

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 to an already approved surgical procedure.

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: 11/5/2015

PROCEDURES:

This Request for Change is only for modification to an already approved surgical procedure. It cannot be used to add a new surgical procedure. The types of modifications that are appropriate include:

- Change in clinical drugs (addition/modification of a reversal agent, local anesthetic, blood thinner, etc...)
- Change in location of incision or cranial burr hole
- Change in wound closure/dressing/cast
- Addition of minor procedure under the same surgical anesthetic event (e.g., bleeding, imaging)
  - The additional procedure must not significantly impact the duration under anesthesia and/or impact the welfare of an animal to a greater extent than that already approved
- Change in surgical outcome from survival to non-survival, with the appropriate scientific justification

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

- The Request for Change must pertain to a non-USDA regulated species
- Clinical drugs must be pharmaceutical grade or compounded with USP diluents
- The change in surgical procedure must be in line with the approved scope of work
- The change in surgical procedure must enhance the quality/quantity of the scientific data obtained or must enhance animal welfare
- The change in surgical procedure must not increase the pain or distress of the animal beyond that already approved
- If a clinical drug or procedure is a hazard, it must already be covered under IACUC SOP 501 (e.g., isoflurane)

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