WVU IACUC POLICY:
Multiple Survival Surgeries in the Same Animal

Introduction

Both OLAW (PHS) and APHIS (USDA) regulate the use of multiple major surgical procedures for research purposes when performed on the same animal (OLAW FAQ F9, Animal Welfare Act Regulations §2.31(d)(ix-x)). From the 2011 Guide for the Care and Use of Laboratory Animals (p. 30): “Surgical procedures in the laboratory setting may be categorized as major or minor (USDA 1985). Whether a procedure is major or minor should be evaluated on a case-by-case basis, as determined by the veterinarian and IACUC (NRC 2003b; Silverman et al. 2007; for additional discussion see Chapter 4, Surgical Procedures). Regardless of classification, multiple surgical procedures on a single animal should be evaluated to determine their impact on the animal’s wellbeing. Multiple major surgical procedures on a single animal are acceptable only if they are (1) included in and essential components of a single research project or protocol, (2) scientifically justified by the investigator, or (3) necessary for clinical reasons. Conservation of scarce animal resources may justify the conduct of multiple major surgeries on a single animal, but the application of such a practice on a single animal used in separate protocols is discouraged and should be reviewed critically by the IACUC. When applicable, the IO must submit a request to the USDA/APHIS and receive approval in order to allow a [USDA] regulated animal to undergo multiple major survival surgical procedures in separate unrelated research protocols (USDA 1985, 1997a). Justifications for allowing animals not regulated by the USDA to undergo multiple survival procedures that meet the above criteria should conform to those required for regulated species. If multiple survival surgery is approved, the IACUC should pay particular attention to animal well-being through continuing evaluation of outcomes. Cost savings alone is not an adequate reason for performing multiple major survival surgical procedures. Some procedures characterized as minor may induce substantial post-procedural pain or impairment and should similarly be scientifically justified if performed more than once in a single animal”.

Background

The WVU IACUC defines major surgeries as any procedure where major body cavities are entered, or that involve more than one tissue plane of dissection (e. g. skin and abdominal muscles, etc.; e. g. skin, periosteum, cranium, dura) to gain entry. Therefore, entry of the abdominal, thoracic, retroperitoneal areas, the cranial vault or limb amputations constitute major procedures. Under this definition, removal of eggs by intracoelomic ovarian tissue removal (no significant deeper tissue planes are dissected), or endoscopic procedures that involve initial incision and blunt trocharization do not meet the definition of major procedures, unless there are added concerns, such as the creation of extensive tissue damage. Likewise, multiple surgical procedures performed on the same animal during the same anesthetic event would not normally constitute multiple survival surgeries under the above definition; instead, the IACUC could reclassify the pain and distress category, or look for alternative remedies if warranted. Extensive surgical exposure during any surgical procedure could necessitate added requirements as determined during the WVU IACUC protocol review process. The projected extent of tissue damage, and anticipated risk of sequelae may trigger the request for a pilot study before full implementation is approved.
Policy

1. This policy does not apply to clinical surgical interventions for the welfare of the animal. Therefore, animals undergoing surgery for medical reasons can still undergo major surgical procedures.

2. The policy does count any surgical procedure defined above as major that occurs prior to the animal arriving at WVU (e.g., animals castrated prior to their arrival) in the total, when that procedure is for a research intent.

3. The use of multiple major surgical procedures needs to be scientifically justified; multiple minor surgical procedures likewise should be described and may also require justification depending on their scope. Space for scientific justification and detailed description of planned multiple survival procedures must be provided in the appropriate appendix of the WVUIACUC protocol; only protocols that provide adequate scientific justification, combined with sufficient detail can be approved by the WVU IACUC. Neither cost nor convenience can be used as the sole basis for approval, although, rarity of the model or species could be a partial justification in some cases.

4. In general, teaching protocols will not be approved by the WVU IACUC for multiple major surgical procedures, unless a research model requires this training; such requests will be examined on an individual basis.

5. Placement of catheters is not considered a major or a minor surgical procedure unless it involves opening of the body cavity (e.g., aortic catheterization). An exception might be cut-down procedure when required.

6. In the case of *Xenopus* or fish species with extensive roe (Sturgeon, etc.), where repeated ovarian tissue biopsies are required for cell biology, embryological or production studies, repeated procedures (at the IACUC’s discretion) may be warranted. The AWIC publication No. 7 (USDA, p. 305) allows up to 6 (euthanized after the 6th collection) uncomplicated ovarian tissue collection procedures per *Xenopus laevis* frog for limited ovarian tissue collections. Even so, each procedure must be separated by a minimum of 3 months of recovery time. After the designated number of successive procedures, or if animals are developing excessive adhesions or other post-surgical complications, the animals are humanely euthanized following the current AVMA euthanasia guidelines.

7. Transfer of animals with surgical histories from one protocol to another or from one research use to another must account for prior surgical uses, and animals should be identified to preclude their inadvertent reuse. Both uses must be scientifically justified with regard to the surgical procedures themselves, not just for use of the animals.

8. USDA/APHIS must be petitioned by the Institutional Official (IO) to allow animals regulated under the Animal Welfare Act (AWA) to be used where the first and second surgeries are unrelated scientifically. Details for an exemption on the limit of multiple major surgeries are submitted to the USDA Animal Care Regional Manager who will forward the request to the appropriate official. The exemption request should contain the following considerations:

   1. An outline of the research proposal for which the procedure(s) is requested;
   2. A means by which to uniquely identify the research proposal;
   3. The species and the approximate number of animals involved in the exemption request;
   4. A method of permanently identifying the individual animals involved;
   5. The time frame for the proposed exempt procedure;
6. The number of major operative procedures to be performed on a given animal, the frequency of such procedures, and the period of time between each major operative procedure;

7. Measures to be taken to ensure that pain/distress are minimized;

8. A complete scientific justification for the exemption. Cost is not an acceptable justification.

9. An assurance that all other stipulated requirements of the AWA and regulations will be met in consideration of this exemption; and

10. An assurance that the facility’s IACUC has approved the exemption.

References

Guide for the Care and Use of Laboratory Animals 8th ed. 2008, NAS Press
Information Resources for IACUC’s. AWIC Resource Series No. 7 2000. USDA. P. 305.