

IACUC POLICY AND PROCEDURE STATEMENT

Policy/Procedure: Surgical Procedures: Definitions and Criteria for Differentiation

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Background

Definition of the term “**surgery**” and classification of surgical procedures as “**minor**” or “**major**” can be ambiguous and a source of confusion for researchers and animal care personnel. In order to alleviate confusion and minimize ambiguity, this Policy and Procedure Statement establishes a working system for classification of various types of surgery, and criteria for differentiation of surgical procedures. The purpose of this statement is to serve as a classification and terminology guide for investigators when preparing Animal Care and Use Protocols, and to assist investigators, the IACUC, and animal care personnel in the process of post-approval monitoring.

Several types of surgical procedures are defined and described in this Policy and Procedure Statement. These definitions are based on definitions and descriptions found in the Animal Welfare Act, the Animal Welfare Regulations, the Merck Veterinary Manual (10th Ed; Kahn, CM and Line, S, Eds), the Textbook of Small Animal Surgery (3rd Ed; Slatter D), the *Guide for the Care and Use of Laboratory Animals*, and the *Guidelines for the Care and Use of Mammals in Neuroscience and Behavioral Research*.

A. Policy

- 1) The BGSU IACUC defines as “**surgery**” any procedure outside of routine non-invasive animal husbandry procedures, performed by investigators or animal care staff under controlled conditions, that involves physical manipulation of an external or internal anatomical feature and that results in alteration (minor or major, either temporarily or permanently) of that anatomical feature.
- 2) The BGSU IACUC adheres to the classification system outlined in the Animal Welfare Act (Section 13(a)(3)(D,E)), which categorizes surgical procedures into three subtypes, as follows:

Non-survival surgery: any surgical procedure in which the animal is anesthetized but is not allowed to regain consciousness prior to euthanasia. This includes any procedure in which surgical manipulations are performed after administration of a lethal dose of anesthetic but prior to death of the animal (as determined by cessation of respiration and cardiac function).

Survival surgery: any surgical procedure in which an animal is expected to fully recover from anesthesia (local or general) following a major or minor surgical procedures. In the case of general anesthesia, any surgical procedure in which the animal is anesthetized, and is then allowed to regain consciousness following the procedure and is expected to fully recover, is considered a survival surgery.

Multiple survival surgeries: this classification applies to any situation in which an animal will be subjected to two (or more) distinct **survival surgery** procedures, as defined above. Bowling Green State University has no written policy regarding multiple survival surgical procedures. The Animal Welfare Act Regulations (9 CFR, Part 2, Section 2.31 (d)(1)(x)) specifically discourage multiple major survival surgeries. However, provisions for conducting multiple survival surgeries may be made on a case by case basis. The BGSU IACUC requires that any protocol in which multiple survival surgical procedures will be conducted provide extensive justification based upon scientific requirements, as specified in the Animal Welfare Act Regulations (9CFR, 2.31). Financial considerations (cost savings) and convenience for the investigator may **NOT** be used as justification for multiple survival surgeries.

- 3) Classification of surgical procedures as “**minor**” and “**major**” surgery, and criteria for differentiation:

Minor surgery is typically a *minimally invasive* surgical procedure involving manipulation of superficial structures of the body, with no incision or a very small incision relative to the size of the animal on which the procedure is performed.

Criteria for categorization of a surgical procedure as “**minor surgery**” are:

- 1) The procedure does not involve opening of the cranium, thoracic cavity, abdominal cavity, or pelvic cavity to expose organs or tissues for surgical manipulation
- 2) The procedure does not include extensive tissue dissection or transection
- 3) Under normal circumstances the procedure does not result in substantial temporary or permanent alteration or impairment of anatomic structure or physiological function of the organ or tissue being surgically manipulated
- 4) The procedure requires only local anesthesia, or short (<15 minutes) general anesthesia with no respiratory assistance.

Examples of minor surgery may include, but are not limited to:

- Epidermal or percutaneous biopsy
- Insertion of subcutaneous implants
- Abscess drainage
- Incision followed by wound closure without tissue or organ manipulation, as might occur in a control or “sham” surgical procedure, given the incision is small relative to the size of the animal as described above

Major surgery is typically regarded as a substantially invasive procedure that will substantially alter (either temporarily or permanently) an anatomical feature (whether internal or external) or physiological function, and may involve opening of body cavities, manipulation of organs, or significant dissection or transection of tissues:

Criteria for categorization of a surgical procedure as “**major surgery**” include, but are not limited to:

- 1) any procedure that requires opening of the cranium, thoracic cavity, abdominal cavity or pelvic cavity to expose organs to surgical manipulation
- 2) any procedure associated with extensive vascular or connective tissue dissection or transection
- 3) any procedure that will result in substantial (either temporary or permanent) alteration or impairment of the anatomic structure or physiological function of the organ or tissue being surgically manipulated
- 4) any procedure performed under general anesthesia that requires respiratory assistance (such as intubation).

Examples of major surgery include, but are not limited to:

- Brain surgery
- Resection or transection of regions of the digestive tract
- Ovariectomy
- Liver cannulation
- Extensive surgical modification of major vascular elements, such as the vena cava, femoral arteries, carotid arteries, jugular veins, etc.
- Organ removal – e.g. unilateral nephrectomy
- Amputation