

Institutional Animal Care and Use Committee (IACUC) Directive 7.0: Surgery in USDA-Regulated Species

1.0 Directive Purpose

The purpose of this directive is to describe the standards for performing surgery in USDA-regulated species used in research.

2.0 To Whom the Directive Applies

This directive applies to all persons responsible for conducting surgery on live USDA-regulated species at Brown University under an IACUC-approved animal use protocol.

3.0 Directive Statement

Surgery in USDA-regulated species must be conducted in accordance with applicable regulatory documents as well as current veterinary medicine practices. The following information is based on the standards set forth in the USDA Animal Welfare Act Regulations, The Guide for the Care and Use of Laboratory Animals, and the Public Health Service Policy.

3.1 Requirements for All Surgical Procedures

3.1.1 Planning Prior to Protocol Submission to the Institutional Animal Care and Use Committee (IACUC):

A veterinarian must be involved with the planning of all surgical procedures; this is most effectively done prior to protocol submission to the IACUC. The purpose of this discussion is to identify the roles of individual personnel, determine any training requirements, to discuss anesthesia/analgesic drugs, the surgical procedure itself and expected outcomes, if any support or equipment is needed, the location where the surgeries will occur, and pre-operative assessment and post-operative care.

3.1.2 Requirements for Principal Investigators (PIs):

- It is the responsibility of the PI to ensure that all personnel are adequately trained in anesthesia administration and monitoring, aseptic technique, good surgical technique, post-procedural support during the recovery period, and record keeping.
- Conduct a continuing and thorough assessment of the surgical outcomes to ensure that the appropriate procedures are followed and potential complications are detected, addressed, and reported as necessary (see the IACUC's Directive on Prompt Reporting).

3.1.3 Training

The PI and all personnel responsible for performing surgery must be trained in the essential elements of good surgical technique listed below. This training can be provided by qualified personnel in the laboratory, by a veterinarian, or by a veterinary technician.

- Asepsis
- Administration of anesthesia and analgesia, including complete monitoring records
- Gentle tissue handling
- Appropriate maintenance and handling of surgical instruments
- Effective hemostasis
- Correct use of suture materials and patterns

3.2 Survival Surgery: All survival surgeries must be conducted following proper aseptic technique. Improper or inadequate technique may lead to infections that may adversely affect animal well-being as well as research results. Aseptic technique includes preparation of the animal, preparation of the surgeon, sterilization of instruments, supplies, and implanted materials, and the use of operative techniques to reduce the likelihood of infection. See '[SOP on Surgery in USDA-Regulated Species](#)' for more information on the survival surgical guidelines in these species.

Survival surgeries may be categorized as major or minor based on the potential for pain and other post-operative complications, the nature of the procedure as well as the size and location of the incisions, the duration of the procedure, and the species, health status, and age of the animal. Based on the category, there are additional regulatory requirements that must be considered.

3.2.1 Major Survival Surgery: A major surgery is one that penetrates and exposes a body cavity, produces substantial impairment of physical or physiological function, and/or involves substantial tissue dissection or transection. Surgical procedures deemed as major must be performed in dedicated surgical facilities. Spaces that are used for other procedures or not operated and maintained under aseptic conditions are inappropriate for surgery on USDA-regulated species.

Performing more than one major survival surgery procedure is only permitted when scientifically justified for a single research project or proposal by the investigator or required for clinical reasons. Cost alone is never an acceptable reason for performing multiple survival surgical procedures. Multiple major survival surgeries must be included by the investigator in their protocol for approval by the IACUC. Other circumstances of multiple major survival surgeries require approval by the USDA Administrator.

3.2.2 Minor Survival Surgery: A minor surgery is one that does not penetrate or expose a body cavity and produces little to no impairment of physical or physiological function. Minor survival surgical procedures do not require a dedicated surgical area or facility. If a non-dedicated facility needs to be used, it should be described and justified in the protocol for approval by the IACUC.

3.3 Nonsurvival Surgery: For non-survival surgeries, it may not be necessary to follow all the requirements outlined for survival surgeries. For nonsurvival procedures of extended duration, attention to aseptic technique may be more important to ensure stability of the model and a successful outcome. See '[SOP on Surgery in USDA-Regulated Species](#)' for more information on the nonsurvival surgical guidelines in these species.



4.0 Definitions

Aseptic Technique: The set of practices and procedures used to reduce microbial contamination during surgical procedures, including perioperative preparation of the surgical space and equipment, the animal, and the surgeon as well as proper surgical technique.

Dedicated Surgical Facility or Area: Space intended for surgery and operated and maintained under aseptic conditions.

Major Surgery: Any surgical intervention that penetrates and exposes a body cavity, produces substantial impairment of physical or physiological function, and/or involves substantial tissue dissection or transection.

Minor Surgery: Any surgical intervention that does not penetrate or expose a body cavity and produces little to no impairment of physical or physiological function.

Nonsurvival Surgery: A surgical procedure during which an animal is euthanized prior to recovery from anesthesia.

Survival Surgery: A surgical procedure from which an animal is expected to completely recover from anesthesia.

USDA-Regulated Species: Any live warm-blooded animal being used or intended for use in research, testing, or experimentation. This term excludes (1) birds, rats of the genus *Rattus*, and mice of the genus *Mus*, bred for use in research, (2) horses not used for research purposes, and (3) other farm animals, such as but not limited to livestock or poultry, used or intended for use as food or fiber, improving animal nutrition, breeding, management, or production efficiency, or for improving the quality of food or fiber.

5.0 Responsibilities

All individuals to whom this document applies are responsible for becoming familiar with and following it. Animal research program stakeholders (IACUC, CARE, ARC) are responsible for promoting the understanding of this document and for taking appropriate steps to help ensure adherence to it.

6.0 Consequences for Violating this Directive

Violation of this directive may be considered a serious event of noncompliance that is reportable to the IACUC, funding and accrediting agencies, as well as other regulatory agencies. Violations are a serious matter that may adversely affect both the ability to perform animal work and acquire funding sources.

7.0 Related Information

Brown University is a community in which employees are encouraged to share workplace concerns with University leadership. Additionally, Brown's Anonymous Reporting Hotline allows anonymous and confidential reporting on matters of concern online or by phone (877-318-9184).

The following information complements and supplements this document. The information is intended to help explain this document and is not an all-inclusive list of policies, procedures, laws and requirements.



BROWN

7.1 Related Policies: N/A,

7.2 Related Polices/Guidelines/SOPs/Directives:

- IACUC Directive on Prompt Reporting
- IACUC SOP on Surgery in USDA-Regulated Species

7.3 Related Forms: N/A

7.4 Frequently Asked Questions: N/A

7.5 Other Related Information:

- **References:**

National Institutes of Health, Office of Laboratory Animal Welfare. 2015. PHS Policy on the Humane Care and Use of Laboratory Animals.

National Research Council. Guide for the Care and Use of Laboratory Animals. 8th ed. Washington, D.C.: The National Academies Press, 2011.

United States Department of Agriculture. Animal Welfare Act and Regulations. USDA-APHIS, 2020.

8.0 Document Owner and Contact

8.0 Owner: IACUC

8.1 Approved by: IACUC

8.2 Subject Matter Contact: Brown University Animal Research Compliance

- Telephone: 401-863-3050
- Email: IACUC@Brown.edu

9.0 History

9.1 Effective Date: 5/4/2018

9.2 Last Reviewed: November 4, 2022

9.3 Update/Review Summary: This Directive is replacing Aseptic Techniques Policy (USDA species), Rodent Surgery Policy and Guidelines for Non-survival (Terminal) and Survival Surgery in Rodents

- IACUC Review 2-12-2021