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	Guidance: Major and Minor Surgical Procedures		
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The intent of this Institutional Animal Care and Use Committee (IACUC) guidance is to define major and minor surgical procedures in research laboratory animals.

Introduction and Background

Both the AWA regulations (9 CFR, Part 2, Section 2.31(d)(1)(x)(A) and (B) and the Guide for the Care and Use of Laboratory Animals (p. 30, 117) require that no animal assigned to a protocol be used for more than one major survival surgery unless the procedures are included within one protocol, are scientifically justified by the investigator, or are necessary for clinical reasons. The Guide states that regardless of classification, multiple survival surgeries on a single animal should be evaluated to determine their impact on the animal's well-being. The following definitions are offered as guidance only. The classification of a surgery as major or minor is ultimately determined on a case-by-case basis by the IACUC and the Attending Veterinarian, with regard to its impact on an animal's well-being.

Survival Surgery

Survival surgery is a surgery from which the animal regains consciousness from anesthesia following the procedure.

Non-survival Surgery

If an animal will be anesthetized so that tissues may be collected and the animal will then be euthanized, the procedure is defined as non-survival surgery. An adaptation of this definition includes surgeries which involve the collection of vital organs (heart, lungs, brain, and blood following exsanguination or perfusion) under anesthesia, which will lead to the imminent death of the animal.

Major Survival Surgery

Major survival surgery is any surgical procedure that penetrates and exposes a body cavity, produces substantial impairment of physical or physiological functions (9 CFR, Parts 1 and 2), or involves extensive tissue dissection or transection (the Guide).

A body cavity is defined as the abdominal, thoracic, cranial, synovial, or bone marrow cavities, i.e. those chambers not immediately associated with the outside world.


Substantial impairment is defined as the circumstance where the animal is not expected to be normal after a reasonable postoperative recovery period. Examples include, but are not limited to, those procedures permanently and significantly affecting ambulation, physiology, the immune system, and mentation.

Examples of major survival surgery include but are not limited to laparotomy, including laparoscopy, thoracotomy, craniotomy, arthrotomy and joint replacement (excluding arthroscopy), orthopedic procedures (e.g. limb amputation), injury models (e.g. head trauma), nerve/muscle transection, eye surgery with corneal incision, significant soft tissue transection, ovariectomy, or nephrectomy.

Major survival surgery requires appropriate anesthesia, analgesia, sterile technique, wound closure (sutures, staples, tissue glue, and/or bandaging), postoperative wound care, and more extensive postoperative monitoring of the animal until healed and/or achieved a normal health status. The IACUC protocol must clearly describe the postoperative care plan and who is responsible for post-operative care.

Minor Survival Surgery

Minor survival surgery is a surgical procedure that does not expose a body cavity and causes little or no physical impairment. Examples include: wound suturing, peripheral vessel cannulation, dehorning, repair of prolapses, and most procedures routinely done on an outpatient basis in veterinary clinical practice. Animals undergoing a minor survival surgical procedure typically do not show significant signs of postoperative pain, have minimal complications, and quickly return to normal function.

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Other examples of minor survival surgery include, but are not limited to, vascular cut-down approach to an artery or vein (e.g. jugular or femoral), tissue biopsy not involving surgical exposure of the body cavity (e.g. skin, muscle, via endoscopy), superficial biopsy involving scientifically justified areas larger than IACUC guidelines (see Table 1), skin or subcutaneous implants, surgical repair of a superficial injury, arthroscopy, oral surgery and tooth extractions not involving bone, closed castrations.

Minor surgery requires appropriate anesthesia, analgesia, sterile technique, wound closure, if applicable (sutures, staples, tissue glue, and/or bandaging), postoperative wound care, and frequent postoperative monitoring of the animal until healed and/or achieved a normal health status. If post-operative care is necessary, the IACUC protocol or amendment must clearly describe the postoperative care plan and who is responsible for post-operative care.

Biopsy

Biopsies are the removal of a piece of tissue from a live animal.

If the collection of tissue involves entering a body cavity, then the biopsy is considered major surgery, as defined above. The exemption is the use of transcutaneous Tru-cut® biopsy needles, fine needle aspirates, or similar techniques of collecting samples of organs within a body cavity.

If the collection of superficial tissues (e.g. skin) exceeds the guidelines set in Table 1, then the biopsy shall be considered a minor surgery (as defined above). Protocols or amendments requiring a biopsied tissue sample greater than those listed in Table 1 will require specific scientific justification and consultation with the Attending Veterinarian before approval by the IACUC.

The collection of superficial biopsy may not necessarily require general anesthesia and may only require subcutaneous instillation of a local anesthetic. With appropriate wound care to prevent infection, biopsies may be allowed to heal by “second intention”, i.e. wound closure may not be necessary with appropriate and frequent cleaning of the area. PIs will consult with the Attending Veterinarian regarding the best possible anesthesia and wound care for the specific biopsy technique.


Table 1. Dimensional skin biopsy guidelines to consider the skin biopsy a “procedure”. Exceeding these guidelines requires specific scientific justification and classification as a “surgery”:

Species	Maximum single “round” biopsy diameter (mm)	Maximum total area of skin biopsies (cm ²)
Mouse	5	0.20
Hamster, gerbil	7	0.40
Rat, guinea pig, ferret	10	0.80
Rabbit, cat, dog, primate	15	1.75
Sheep, pig	20	3.25

Multiple Survival Surgery

Multiple survival surgery is when more than one survival surgery (major or minor) is performed on a single animal.

Multiple survival surgical procedures on a single animal are discouraged. Multiple survival surgeries on a single animal may be permitted only if scientifically justified by the investigator and approved by the IACUC. The number of survival surgeries performed must be limited to the minimum number necessary to achieve the research objectives and must be determined with due consideration for minimizing the pain and distress experienced by any one animal. Whenever possible, all operative procedures should be done at one time to minimize post-operative discomfort and distress to the animal. Cost or convenience is not adequate justification for the conduct of multiple survival surgeries.

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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 USDA/APHIS and receive approval in order to allow a regulated animal to undergo multiple major survival procedures in separate unrelated research protocols (USDA 1985, 1997a). Justification for allowing unregulated animals to undergo multiple survival surgeries that meet the above criteria should conform to those required for regulated species.

Multiple major survival procedures on a single animals are permitted only under the following circumstances:

1. Essential components of a single research protocol in which other methods will not achieve the research goals.
2. Scientifically justified by the principal investigator and approved by the IACUC. Cost savings alone are not sufficient justification for multiple survival surgeries (the Guide, p. 30). Justification must include an explanation of the need to have an animal undergo multiple major survival surgeries, a description of the procedure(s), the total number of surgeries an animal will undergo, the frequency of the procedure, the period of time between procedures, and the methods used to minimize pain and distress. It is recommended that the investigator provide references when possible.
3. Necessary for clinical reasons and approved by the AV.

References

1. Animal Welfare Act and Animal Welfare Regulations. Part 2 – Regulations; Subpart C – Research Facilities; § 2.31, c, (4), and § 2.32, c, (4). United States Department of Agriculture: Washington, DC, 2013. http://www.aphis.usda.gov/animal_welfare/downloads/Animal%20Care%20Blue%20Book%20-%202013%20-%20FINAL.pdf
2. Public Health Service Policy on Humane Care and Use of Laboratory Animals. U.S. Department of Health and Human Services, National Institutes of Health, Office of Laboratory Animal Welfare. 2015.
3. *Guide for the Care and Use of Laboratory Animals*, 8th Ed., National Research Council; National Academy Press: Washington, DC, 2011. <http://www.nap.edu/catalog/12910/guide-for-the-care-and-use-of-laboratory-animals-eighth>
4. University of Pennsylvania IACUC. IACUC Guideline 13: Surgical Definitions and Biopsy Guidelines.
5. University of California, Los Angeles. Office of Animal Research Oversight. Policy: Multiple Survival Surgeries.