FIU FLORIDA INTERNATIONAL UNIVERSITY

SOP #: 102.02

Title: SOP - Surgery

Approvals:

Attending Veterinarian _____ **Date:** 8/12/16

IACUC Chairman _____ **Date:** 03.18.16

1. Purpose

1.1 The intent of this SOP is to describe methods of surgery which have been approved by Florida International University - Institutional Animal Care and Use Committee (IACUC). Following these procedures will ensure compliance with animal care and use at FIU. Any exemptions to this SOP must be submitted to and approved by IACUC prior to their application.

1.2 AWA regulations require that survival surgeries be performed using aseptic techniques and that major operative procedures on non-rodents be performed only in dedicated surgical facilities. For the purposes of this policy, designated surgical facilities are those that are set up to be cleaned and maintained in an aseptic condition, and are not used for other purposes when they are not being used for surgery. They must be maintained in good repair to meet aseptic requirements.

1.3 As a general principle of animals used in research, multiple survival surgical procedures on a single animal are typically discouraged. Multiple major survival surgical procedures may be justified if they are related components of a research project, if they conserve scarce animal resources, or if they are needed for clinical reasons. Cost savings is not an adequate reason for performing multiple major survival surgical procedures. The investigator must provide a written explanation as detailing the justification for multiple survival surgeries to the IACUC for review and approval.

1.4 In non-survival surgery, it may not be necessary to follow all the procedures outlined in this SOP but at minimum the surgical site should be clipped, the surgeon should wear gloves and the instruments and surrounding area should be clean. For non-survival surgeries of extended duration, aseptic technique should be followed to ensure the stability of the

model. The IACUC will assess each situation individually during animal study protocol review.

1.5 Exceptions – For an animal that requires an emergency operative procedure as part of proper veterinary care, this emergency procedure does not require IACUC approval and it is not considered as part of the number of surgeries conducted for regulatory proposes.

2. Responsibility

2.1 It is the responsibility of all personnel using animals in research and teaching to abide by this policy. It is the responsibility of the IACUC to review for approval properly justified requests for an exception to this policy.

3. Definitions

3.1 Major surgery: Penetrates and exposes a body cavity (such as cranium, thorax, abdomen), produces substantial impairment of physical or physiologic functions or involves extensive tissue dissection or transection

3.2 Minor surgery: does not expose a body cavity and causes little or no physical impairment (such as wound suturing, peripheral vessel cannulation, etc).

3.3 Survival surgery: the animal is allowed to recover following the surgery.

3.4 Non-survival surgery: the animal is euthanized before recovery from anesthesia.

3.5 Multiple survival surgery: more than one surgery is performed on one animal that is allowed to recover from anesthesia.

3.6 Laparoscopic surgeries may be classified as major or minor surgery depending on the impact on the animal.

4. Guidelines

4.1 Pre-surgical planning shall include an approved IACUC protocol along with input from all members of the surgical team, including the anesthetist, veterinarian, surgical technicians, animal care staff, investigator, etc.

4.2 The pre-surgical plan shall identify personnel, their roles, training needs, equipment and supplies required for the procedures planned. The surgical plan shall also involve the preoperative animal-health assessment and postoperative care.

4.3 Training of personnel: surgical techniques training shall be provided on:

4.3.1 Asepsis

4.3.2 Tissue handling and minimal dissection of tissue

4.3.3 Appropriate use of instruments and correct use of suture materials

4.3.4 Effective hemostasis

4.4 For USDA regulated species, all surgeries must be performed in a dedicated surgical suite.

4.5 For Non-USDA-Regulated Survival Surgery - unlike the requirements for a USDA surgical suite, the space does not need to be dedicated to surgery all the time. The surgery area and associated equipment must be organized, sanitized and dedicated to that purpose while surgery is conducted. The surgery can also be conducted under a laminar flow procedure

hood. If a surgery is to be performed outside the Animal Care Facility, surgery must be done in an isolated area of a laboratory, away from the flow of traffic and where contamination from other non-surgical related activity is minimized.

4.6 All surgical work surfaces must be thoroughly cleaned with an approved surface disinfectant prior to and after each procedure.

4.7 Since most bacteria are carried on airborne particles, the surgical facility/area shall be maintained and operated in a manner that ensures cleanliness and minimizes unnecessary traffic.

4.8 Pre-operative procedures

4.8.1 Surgeon's preparation:

4.8.1.1 Wear a surgical mask and a sterile gown

4.8.1.2 Wash hands

4.8.1.3 Use aseptic technique. Wear sterile surgical gloves.

4.9 Animal preparation

4.9.1 The withholding of food and water from mice, rats and rabbits prior to surgery is not necessary unless it is called for in an IACUC approved protocol. If withholding of food is necessary it must be discussed with the Attending Veterinarian. For pigs, the morning meal will be skipped to prevent aspiration pneumonia.

4.9.2 Hair must be removed from at least 3 cm around the surgical site. Hair can be removed by shaving with a razor, plucking a small area while the animal is under anesthesia, or by using a depilatory cream (i.e. Nair). Adhesive tape can be used to minimize loose hairs near the surgical site.

4.9.3 An animal must be anaesthetized at an appropriate depth of anesthesia prior to surgical commencement. An indicative sign of proper depth of anesthesia includes lack of physical response to a toe pinch and relaxed and regular respiration, as well as other specific signs (heart rate, blood pressure, jaw tone and eye position in larger animals) .

4.9.4 Since rodents are prone to hypothermia while under anesthesia, the animal should be placed on a heating pad with a “low” setting or use latex gloves filled with warm water placed alongside the animal to minimize the risk. Surgical tables for large animals are heated and these can also be used for rodent surgeries.

4.9.5 Place a small amount of a sterile ophthalmic ointment in each eye to protect from drying.

4.9.6 The animal should be covered with a sterile drape to prevent sutures from coming into contact with hair and skin around the surgical area. For minor incisions, the drape can be placed only when suturing the wound. Note: For rodents, surgical drapes must be sterile for the first animal, and may then be transferred to the following animal during serial surgeries. The top surface of the drape must never come in contact with non-aseptic areas, and must not be soiled.

4.10 Surgical Principles

4.10.1 Materials and Instruments:

4.10.1.1 Sterile surgical instruments. Sterilization with heat is ideal but other forms of sterilization such as chemical or gaseous sterilants are acceptable. Glass bead sterilization is acceptable only for Non-USDA-Regulated species and for sterilizing instruments while surgery is in progress.

4.10.1.2 Sterile gauzes

4.10.1.3 Suture material

4.10.1.4 Dry bead sterilizer for rodent surgeries.

4.10.1.5 Skin staples

4.10.2 Before entering the surgical field, all individuals involved must wear the following: Bouffant cap, surgical mask, surgical gloves and a clean surgical gown or designated lab coat. Hands and forearms must be washed thoroughly with antimicrobial hand scrub prior to placing on gloves.

4.10.3 Prior to surgery, the depth of anesthesia is verified by the loss of animal's pedal withdrawal reflex and check that all the available materials are at hand. Begin surgery with clean and sterile surgical instruments.

4.10.4 Designate a sterile area on the working surface for the sterile material (instruments, suture material, drapes, gauze, etc.).

4.10.5 Use a scalpel blade or scissors to make the smallest possible incision.

4.10.6 Avoid contact of tissues with fingers by using the tip of instruments.

4.10.7 If any organs are exposed for long periods of time during the surgical procedure, it must be periodically lavaged with warm sterile saline or covered with a saline-soaked sponge.

4.10.8 Close the different tissue layers separately, such as peritoneum/abdominal muscles layer together and subcutaneous tissue and then skin. For some surgeries, subcutaneous tissue may need to be sutured independently from the skin to prevent dead space. For peritoneum and abdominal muscle use Vicryl, or Polypropylene suture material; size 3-0 or 4-0.

4.10.9 Skin is closed using staples, sutures or surgical glue.

4.10.10 In case of serial surgeries, for large animals, use a new surgical pack for each animal. For rodent surgeries, the instruments must be aseptized between each animal by dipping them in a dry heat bead sterilizer for approx. 10 seconds and then rinsed with sterile saline for cooling. Suture material can be dipped in 70% alcohol between each animal.

4.11 Surgical Monitoring and Supportive Care

4.11.1 Surgeries exceeding 15 minutes for mice or 30 minutes for rats require a contact heat source to prevent hypothermia.

4.11.2 Adjust the depth of anesthesia according to monitored parameters (presence of reflexes, the respiratory rate and breathing pattern, and when available, the heart rate and Pulse Oximetry.

4.11.3 In the case of respiratory arrest, stop anesthesia, administer oxygen and compress the thorax rapidly.

4.12 Postoperative Care

4.12.1 The Principal Investigator and the Attending Veterinarian share responsibility for ensuring that post-surgical care is appropriate.

4.12.2 A record of the surgical procedure must be kept for each animal that under goes survival surgery. The record should contain and outline physiological responses such as body temperature, respiratory pattern, drugs used, dosages, routes of administration and all complications that arise from the procedure. All information provided should be as quantitative as possible but qualitative data is acceptable.

4.12.3 Postoperative care begins immediately following surgery and extends up to 10 days depending on the type of surgery.

4.12.4 During the anesthetic-recovery period the animal(s) shall be in a clean, dry area to be observed by trained personnel until it regains righting reflexes. Prevent heat loss and if necessary maintain the animal in contact with a heat source. Administer oxygen if necessary.

4.12.5 Repeat analgesics post-surgically and for the next few days if required according to the approved animal study protocol or as instructed by the Attending Veterinarian.

4.12.6 For Rodents administer warm isotonic fluids SC for surgeries exceeding 30 minutes at a dose of 0.2–0.5 mL/10 g body weight for mice and 1.0-1.5 ml/100g body weight for rats. Fluids can be administered on the following days, to help speed up recovery.

4.12.7 Surgical sites must be monitored for inflammation, infection, and bleeding twice a day for the first three days post-surgery, and once a day thereafter for seven days or until the animal returns to normal in behavior and physical appearance. If the surgical wound shows any signs of abnormal healing, consult the Attending Veterinarian for an examination of the animal.

4.12.8 Monitoring shall include:

- 4.12.8.1 Function of intake and elimination
- 4.12.8.2 Behavioral signs of postoperative pain
- 4.12.8.3 Monitoring for postoperative infections
- 4.12.8.4 Monitoring of the surgical incision
- 4.12.8.5 Bandaging as appropriate
- 4.12.8.6 Timely removal of skin staples

4.13 Suggestions to consider

4.13.1 When performing multiple surgeries having an assistant can be invaluable. Not only will it save time but also would help in minimizing contamination and have the process flow more efficiently. For example, an assistant can shave and scrub the next animal for surgery while the surgeon is closing an incision on the first animal. An assistant can remove the first animal to recovery and place the second in the surgical field so that the surgeon's hands remain as sterile as possible. An assistant can observe and care for the animal post operatively, performing all the post-operative monitoring paperwork while the surgeon is working on the second animal.

4.13.2 Considering performing all survival surgical procedures when an Animal Care Facility staff member is on duty. They can be there to provide you with assistance as well as act as a backup monitoring for the animals in case the surgeon is not able to do so.

5. References

5.1 Animal and Plant Health Inspection Service, USDA 9 CFR, Chapter 1, Subchapter A-Animal Welfare, U.S. Government 1-1-92 Edition.
5.2 Animal and Plant Health Inspection Service, USDA, Policy #3 --- Veterinary Care--- March 25, 2011.
5.3 PHS Policy on Humane Care and Use of Laboratory Animals (p. 13)
5.4 Guide for the Care and Use of Laboratory Animals, Institute of Laboratory Animal Resources, National Research Council, 8th Ed. 2011 (p. 115-120).
5.5 U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training.

6. Revision

6.1 Revision 02: 2016 IACUC Review – 4.4 included the requirement for surgery of regulated species to be performed in a dedicated surgical suite. 4.9 included addition of pigs and rabbits, as well as requirement for vital signs monitoring.