



BROWN

## **Institutional Animal Care and Use Committee (IACUC): Standard Operating Procedure (SOP) on Surgery in USDA-Regulated Species**

### **1.0 SOP Purpose**

The purpose of this SOP is to provide guidance to personnel conducting survival surgical procedures on species covered by the Animal Welfare Act.

### **2.0 Survival Surgery**

All survival surgical procedures performed on USDA-covered species must follow the general principles of asepsis. Aseptic technique is used to reduce microbial contamination to the lowest practical level; includes preparation of the patient, surgeon, and instruments; and requires adherence to certain practices throughout the procedure.

#### **2.1 Dedicated Operating Room Requirement**

The USDA regulations require that all survival surgeries involving USDA-covered species be done in a dedicated operating room. Information regarding the location and use of operating rooms can be found by contacting the Center for Animal Resources and Education (CARE) at [care@brown.edu](mailto:care@brown.edu).

#### **2.2 Preparation of the Animal**

Animal preparation must occur in an area separate from the operating room and after the animal is sedated/anesthetized. Preparation must include the following:

- Placing ophthalmic ointment in both eyes to prevent drying of the cornea during surgery.
- Removal of hair/fur from the surgical site and from areas where any electrodes may be placed. This is important to create a clean field for surgery as well as for monitoring equipment that requires contact with the skin. Removal is typically accomplished using clippers. The shaved area should be wide enough to avoid contamination from the surrounding skin and hair during surgery but should be the minimum area compatible with achieving an appropriate sterile field. Removing more hair than necessary predisposes the animal to hypothermia during the surgical procedure.
- Any hair/fur that has been removed, along with any gross debris, must be cleaned away using a vacuum and/or alcohol.
- If there is any dirt or debris present at the intended surgical site, the area must be cleaned with a surgical scrub and rinsed with alcohol and/or saline.

Following completion of the above procedures, the animal should then be moved into the operating room. Once the animal has been moved into the operating room, preparation of the animal is continued.

- The anesthetized animal must be properly secured to the operating table using a species-appropriate restraint. This minimizes excessive movement of the animal during surgery and [the potential for] a resulting breach in sterility. Care must be taken not to overtighten any restraints as this may result in vascular occlusion or muscle/nerve damage.

- The skin must be disinfected using a concentric surgical scrub pattern moving from the innermost to outermost portions of the shaved area. Warming solutions to body temperature will increase their effectiveness and reduce the risk of causing hypothermia. The below approaches may be used for disinfecting the skin:
  - One-step alcohol-based solutions, such as ChlorPrep or DuraPrep.
    - A single application is sufficient and no rinsing is required. Apply the solution with a sterile applicator using sterile gloves until a uniform application is achieved over the surgical site.
    - Allow the surgical site to dry for 2-3 minutes before draping.
  - Antiseptic scrub alternated with alcohol or sterile water and followed with antiseptic solution
    - Antiseptic scrubs contain a detergent solution whereas the solution does not. Chlorhexidine or povidone-iodine antiseptic scrubs and solutions may be used
    - Apply these materials using sterile gauze, sterile solutions, and sterile gloves.
    - Apply one of the scrubs specified above using a concentric surgical scrub pattern, followed by alcohol or sterile water.
    - Repeat this alternating prep three times.
    - After three scrubs, allow the site to dry and then apply a final preparation of antiseptic solution.
    - Allow the final solution to dry for five minutes before draping the animal.
- Drape the animal using sterile drapes of sufficient size to cover all unprepared parts of the animal and adjacent surfaces. The only part of the animal not covered must be the properly prepared surgical site. It is important to provide sufficient space for the surgeon to use instruments and suture material without accidentally contacting non-sterile surfaces.

### **2.3 Preparation of the Surgeon and Surgical Assistant(s)**

Surgeons, and any other person who will have contact with the sterile surgical field during the surgery (collectively, surgical assistants), must prepare for surgery in the following manner:

- Don appropriate personal protective equipment (PPE) for the species and Animal Biosafety Level (ABSL). The minimum PPE includes clean scrubs, an appropriate face mask, a hair bonnet, closed-toe shoes, and shoe covers. In the case of surgery involving nonhuman primates, a face shield is also required. Place the face mask and hair bonnet before scrubbing, gowning, and gloving. Those individuals with beards must use masks that are large enough to cover their facial hair.
- Remove all jewelry from hands and wrists. A complete surgical scrub is to be performed in the surgeon's scrub area adjacent to the operating room. This includes scrubbing both hands, in between fingers, and both forearms with a designated surgical scrub brush with an antibacterial soap.
- Don a sterile surgical gown and sterile surgical gloves of the correct size using appropriate technique so as to not contaminate the outside of the gloves or the front of the gown.
  - The gown should be put on by the surgeon and the gown ties tied at the back by a surgical assistant.
  - The outer packet of gloves must be opened either by the surgeon before scrubbing or by a surgical assistant. The internal sterile packing containing the gloves should be touched only by the surgeon.

- Once the surgeon is wearing sterile clothing and gloves, take care to avoid touching non-sterile items, such as the table, anesthetic equipment, or operating lights. The presence of a surgical assistant is strongly recommended in order to make any adjustments requiring non-sterile equipment.
  - If the surgeon touches a non-sterile item/surface, the surgeon must don a new sterile pair of gloves.
  - If it is necessary for the surgeon to leave the surgical suite during a procedure, re-scrub and don a new surgical gown and new gloves before reentering.

Non-surgeons that will not have contact with the sterile field must wear appropriate PPE, including a disposable cover gown, a mask, a hair bonnet, shoe covers, and gloves. Nonhuman primate surgeries also require a face shield. Surgical assistants that have not scrubbed in must not touch sterile instruments, drapes, or consumables.

#### **2.4 Preparation and Handling of Surgical Instruments, Equipment, or Implanted Material, and Consumables**

All surgical instruments must be cleaned and autoclaved prior to use on animals for all surgical procedures.

- Autoclaved surgical packs must contain a sterilization indicator, the date of sterilization, and expiration date for the pack.
- Surgeons and/or surgical assistants must check the indicator/mark on packaged instruments and confirm that the outer packaging has not been breached. This will ensure that the sterilization process has been effective.

Equipment or implants that will come into contact with the sterile field that are unable to withstand the conditions of autoclaving must be sterilized in another way.

- Ethylene oxide sterilization is available through CARE for a fee. It is important to plan ahead for the time it takes for processing and subsequent off-gassing.
- Cold sterilization should only be used as a last resort when other methods are not appropriate. A specific cold sterilant must be used and the manufacturer's instructions must be strictly followed. The instruments must be rinsed with sterile water or sterile saline before putting them in contact with animals.

A new set of sterile instruments must be used for each animal. Plan ahead to ensure there are enough sets of sterile instruments to cover the number of animals that will undergo surgery that day.

All consumables that will be used during the procedure (e.g., gauze, swabs, needles, suture materials) must be sterile and should be of an appropriate size and packaged in suitable quantities.

#### **2.5 Recordkeeping**

It is essential that surgery and all post-procedural care adhere to what is described in the related approved IACUC protocol. As the medical records are the primary method of assessing procedural and animal care compliance with the protocol, accurate and detailed records must be kept. Generally, there are three documents used to record procedures:

### **2.5.1 Procedure Report**

At a minimum, the following information must be included in the surgical records:

- Date of procedure
- Principal investigator (PI) name and IACUC protocol number
- Species and identification number
- Names of all participating personnel (i.e., surgeons and anesthetists)
- Detailed description of the procedure
- Any deviations from the procedure, as approved in the protocol, due to emergency or unforeseen circumstances must be documented and explained

### **2.5.2 Anesthesia Record**

At a minimum, the following information must be included in the anesthesia record:

- PI name and IACUC protocol number
- Species and identification number
- Date and location of procedure
- General procedures, including but not limited to: number of intubation attempts, beginning and end of the procedure, time of extubation, etc.
- Significant procedural events and time of occurrence. For example, primary incisions, vessel ligation, start of cardiopulmonary bypass, drilling sites for craniotomy.
- Any complications should be noted, including the time of occurrence and any interventions
- Any analgesics, anesthetics, antibiotics, and all other drugs administered, including dose, route, and time provided
- Vital signs appropriate to the species should be recorded with frequency (generally every 5 - 10 minutes). The body temperature should be documented at least every 15 minutes. Other monitoring techniques (i.e., blood pressure, pulse oximetry, ECG) should be performed at similar intervals

See [USDA Anesthesia Monitoring Record](#) as an example form that can be used as-is or modified for use with specific surgical procedures.

### **2.5.3 Postoperative Monitoring**

At a minimum, the following information must be included in the postoperative monitoring records:

- PI name and IACUC protocol number
- Species and identification number
- Date and time of postoperative observations (include AM/PM).
- Initials of individuals conducting the observations/care
- Condition of the animal should be evaluated. Any abnormalities in clinical condition or behavior (differing from a normal, healthy, awake animal) must be noted in the clinical record and reported to a CARE veterinarian.
  - Mentation (i.e., bright, quiet, dull)
  - Vital signs (i.e., temperature, heart rate, respiratory rate, appetite, gastrointestinal and bladder function)

- Pain assessments should be performed, at a minimum, with each scheduled administration of analgesics. A negative pain assessment (i.e., pain-free state) must be observed and documented prior to discontinuing analgesic administration. Departure from protocol-approved analgesia regimens should be communicated to the CARE veterinarian.
- Appearance of surgical sites (i.e. signs of adverse reactions or potential infection)
- Any analgesics, antibiotics/microbials, and all other drugs administered, including dose, route, and time provided. Time intervals for administering medications must be strictly adhered to per the approved protocol.

## **2.6 Nonsurvival Surgery Guidelines**

For non-survival surgeries, it may not be necessary to follow all the requirements outlined for survival surgeries. However for procedures of extended duration, attention to aseptic technique may be more important to ensure stability of the model and a successful outcome. The following guidelines describe the minimum requirements for nonsurvival surgery on USDA-regulated species.

### **2.6.1 Preparation of the Animal**

The hair around the surgical site should be removed with clippers and the area should be clean and free of gross debris.

### **2.6.2 Preparation of the Surgeon and Surgical Assistants**

Don appropriate personal protective equipment (PPE) for the species and Animal Biosafety Level (ABSL). The minimum PPE includes clean scrubs, an appropriate face mask, a hair bonnet, closed-toe shoes, and shoe covers. In the case of surgery involving nonhuman primates, a face shield is also required. The surgeon does not have to don sterile attire but needs to wear a clean gown and gloves.

### **2.6.3 Preparation and Handling of Surgical Instruments, Equipment, or Implanted Material, and Consumables**

Instruments should be clean and free of gross debris. Nonsterile instruments and supplies are acceptable. It is not acceptable to use any expired goods or materials.

### **2.6.4 Recordkeeping**

It is essential that surgery and all post-procedural care adhere to what is described in the related approved IACUC protocol. As the medical records are the primary method of assessing procedural and animal care compliance with the protocol, accurate and detailed records must be kept. Generally, there are three documents used to record procedures:

### **2.6.5 Procedure Report**

At a minimum, the following information must be included in the surgical records:

- Date of procedure
- Principal investigator (PI) name and IACUC protocol number
- Species and identification number
- Names of all participating personnel (i.e., surgeons and anesthetists)
- Detailed description of the procedure
- Any deviations from the procedure, as approved in the protocol, due to emergency or unforeseen circumstances must be documented and explained

### **2.6.6 Anesthesia Record**

At a minimum, the following information must be included in the anesthesia record:

- PI name and IACUC protocol number
- Species and identification number
- Date and location of procedure
- General procedures, including but not limited to: number of intubation attempts, beginning and end of the procedure, time of extubation, etc.
- Significant procedural events and time of occurrence. For example, primary incisions, vessel ligation, start of cardiopulmonary bypass, drilling sites for craniotomy.
- Any complications should be noted, including the time of occurrence and any interventions
- Any analgesics, anesthetics, antibiotics, and all other drugs administered, including dose, route, and time provided
- Vital signs appropriate to the species should be recorded with frequency (generally every 5 - 10 minutes). The body temperature should be documented at least every 15 minutes. Other monitoring techniques (i.e., blood pressure, pulse oximetry, ECG) should be performed at similar intervals

See [USDA Anesthesia Monitoring Record](#) as an example form that can be used as-is or modified for use with specific surgical procedures.

### **2.6.7 Final Disposition**

The method of euthanasia as well as confirmation of death must be recorded.

## **3.0 Definitions: N/A**

## **4.0 Responsibilities**

All individuals to whom this SOP applies are responsible for becoming familiar with and following this SOP. University supervisors are responsible for promoting the understanding of this SOP and for taking appropriate steps to help ensure compliance with it.

## **5.0 Related Information**

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

### **5.1 Related University Policies: N/A**

### **5.2 Related SOPs: N/A**

### **5.3 Related Forms:**

- USDA Anesthesia Monitoring Form

### **5.4 Frequently Asked Questions (FAQs):** N/A

### **5.5 Other Related Information:** References:

- Fossum, Theresa W. Small Animal Surgery. 4th ed., Elsevier Mosby, 2013.
- Lilley, E, and M Berdoy, editors. Guiding Principles for Preparing for and Undertaking Aseptic Surgery. 2nd ed., Laboratory Animal Science Association, 2017.
- National Research Council. Guide for the Care and Use of Laboratory Animals. 8th ed. Washington, D.C.: The National Academies Press, 2011.
- Office of Laboratory Animal Welfare. Public Health Service Policy on Humane Care and Use of Laboratory Animals. National Institutes of Health, 2015.
- United States Department of Agriculture. Animal Welfare Act and Regulations. USDA-APHIS, 2020.

## **6.0 SOP Owner and Contact(s)**

### **6.1 SOP Owner:** IACUC

### **6.2 SOP Approved by:** IACUC

### **6.3 Subject Matter Contact:** Brown University Animal Research Compliance (ARC)

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

## **7.0 SOP History**

### **7.1 SOP Issue Date:** October 7, 2022

### **7.2 SOP Effective Date:** October 7, 2022

### **7.3 SOP Update/Review Summary:** The SOP was updated to include both survival and non-survival surgery information.