

Policies and Procedures

SECTION: IACUC	NUMBER: 7.11			
CHAPTER: Miscellaneous Experimental Animal Use Policies	ISSUED: 11/2005	REV. A: 4/7/2009	REV. B: 11/2012	REV. C: 11/2014
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Purpose

The purpose of this policy is to describe clear guidelines for aseptic surgery. This procedure is approved by the Creighton University Institutional Animal Care and Use Committee (IACUC). All investigators will follow this policy unless scientific justification is provided and approved by the IACUC.

Application

Policy describes the standard of veterinary care expected to be provided by Principal Investigators who perform aseptic surgical procedures as outlined in a Creighton University IACUC approved animal protocol. Animal surgical procedures must be conducted in accordance with the requirements of:

- The most recent *Guide for the Care and Use of Laboratory Animals* (The Guide) National Research Council of the National Academies
- Animal Welfare Regulations (AWR, CFR 1985), and
- Public Health Service Policy on Humane Care and Use of Laboratory Animals (PHS Policy, 1996).

The "Guide" classifies surgical procedures under the category of Veterinary Medical Care. It specifically states that: "successful surgical outcomes require appropriate attention to pre-surgical planning, personnel training, anesthesia, **aseptic and surgical technique**, assessment of animal wellbeing, appropriate use of analgesics, and animal physiologic status during all phases of a protocol involving surgery and post-operative care. The individual impact of those factors will vary according to the complexity of procedures involved and the species of animal used. A team approach to a surgical project often increases the likelihood of a successful outcome by providing input from persons with different expertise." It further states that:

"Aseptic technique is used to reduce microbial contamination to the lowest possible practical level. No procedure, piece of equipment, or germicide alone can achieve that objective. Aseptic technique requires the input and cooperation of everyone who enters the operating suite. The contribution and importance of each practice varies with the procedure.

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Aseptic technique includes:

- Preparation of the patient; such as hair or feather removal and disinfection of the operative site.
- Preparation of the surgeon such as the provision of appropriate surgical attire, face masks, and sterile surgical gloves.
- Sterilization of instruments, supplies, and implanted materials; and
- The use of operative techniques to reduce the likelihood of infection.”

The purpose of the following guidelines is to assist the investigators in complying with these requirements. In general, unless an exception is specifically justified as an essential component of the research protocol and approved by the IACUC, the investigators should follow these guidelines.

Responsibility

The major responsibility for animal protection and monitoring during and after a procedure lies with the Principal Investigator (PI). Any instances in which a PI or staff member fails to provide veterinary care in accordance with this policy is considered an infraction by the Creighton University IACUC and may result in suspension of a protocol and/or the privilege of an individual to perform animal research. Serious infractions may result in a loss of the ability to utilize data generated as a result of the study. This policy applies to any Creighton University Investigators, Co-Investigators, Post-doc/Fellow, Technician, Graduate Student, Undergraduate Student and Visiting Scientists. It is the responsibility of the PI to ensure that all individuals involved in a procedure on an animal are aware of their duties and responsibilities, the appropriate contact individuals should problems arise during or after a procedure, and that all individuals read and understand this policy.

Principles of Surgical Techniques

- All items used in any surgical procedure must be sterilized.
- Persons who have scrubbed should touch only sterile items. Persons who have not scrubbed should touch only non-sterile items.
- If the sterility of any items is in doubt it should be considered non-sterile.
- If a non-scrubbed person touches a sterile table, re-drape the table.

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- If a scrubbed person touches a non-sterile table that person should re-gown or cover the contamination.
- Any sterile table or sterile item left unguarded or uncovered should be considered non-sterile.
- If the autoclave tape is only partially changed in color the item should be considered non-sterile.
- When preparing for surgery, personnel should:
 - First put on a cap and then a mask.
 - Scrub from fingers to 2-3 inches above elbow.
 - Open gown and glove packs and put on gown and gloves.
- Persons who have not scrubbed should avoid reaching over sterile fields and those who have scrubbed should avoid leaning over non-sterile areas.
- The scrubbed person should set basins to be filled at the end of the table.
- The circulator should stand at a distance from the sterile field when adjusting the light.
- The surgeon should turn away from the field to have his/her brow mopped.
- The scrubbed person should drape the sterile tables nearest him/her first.
- Tables are considered sterile only at tabletop level or above.
- Linen or sutures falling below table level are considered non-sterile and discarded.
- When draping the table the part of the sheet that drops below the table surface should not be brought up to table level again.
- Gowns are considered sterile only from waist to shoulder level and in front or on the sleeves.
- While scrubbing, keep hands in sight above waist level, and away from the face.
- When standing on stools, the area of the gown below the waist must not brush against the sterile table.
- Arms should never be folded; perspiration in the axillary region may lead to contamination.
- Articles dropped below waist level must be discarded.
- Scrubbed persons should keep well within the sterile area. A wide margin of safety should be allowed when passing non-sterile areas.
- Scrubbed persons should:
 - Keep a safe distance from the operating table when draping the patient.
 - Pass each other back to back.
 - Turn their back to a non-sterile area when passing.
 - Face a sterile area when passing it.

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- Ask a non-scrubbed person to step aside rather than trying to crowd past him/her.
- Stay near and facing the sterile tables if waiting for the animal to be prepped.
- Persons who have not scrubbed should avoid sterile areas. If a person who has not scrubbed must pass a sterile area he/she should face the area when passing to make certain it has not been touched.
- Moisture allows bacteria to the sterile area causing contamination
- Sterile packages should be laid only on dry areas.
- If a sterile package becomes damp or wet, it should be re-sterilized or discarded.
- If a solution soaks through a sterile drape to a non-sterile area, the wet area should be covered with another sterile drape.
- When bacteria cannot be eliminated from a field, they should be kept to an irreducible minimum. Patient skin cannot be sterilized and is a source of potential contamination from both the patient and members of the operating team. To minimize contamination potential:
- The patient is shaved and scrubbed in the prep area (Betadine scrub followed by Isopropyl alcohol rinse will be performed twice) and is given a final sterile scrub (final Betadine scrub and Isopropyl alcohol rinse followed by a Betadine solution paint which will be allowed to dry) will be performed in the operating room.
- When draping, all skin should be covered except the site of incision.
- All surgeons and assistants must scrub their hand and arms.
- All surgeons and assistants must gown and glove without touching the outside of the gown and gloves.
- Hand towels should not touch scrub suits while drying hands after scrubbing.
- In some cases the knife blade used for the skin incision should be considered contaminated and should not be used deeper than the skin.
- If a glove is contaminated during the procedure it must be changed at once. If an instrument punctures the glove, the instrument must also be handed off.

Note:

All drugs, medical supplies, and sterilized items used during surgery must be current. No outdated material can be used.

Cleaning Instruments

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Prior to sterilization, all instruments must be cleaned to remove debris, blood, oil, etc. The two common methods of cleaning include:

Manual Cleaning

- Rinse the instruments in tap water as soon as surgery is over. This prevents blood from drying in serration and box locks.
- Open all box locks and disassemble instruments.
- Scrub each instrument with a soft brush in warm water with an instrument detergent with a pH near 7.0-8.5. Wear gloves and be mindful of sharp edges on instruments.
- Inspect each instrument for proper function and cleanliness; particularly box locks, grooved ends, and other areas not readily exposed.
- Rinse the instruments with water (distilled if available) to ensure removal of detergent. Distilled water is used to prevent mineral deposits on the instrument surfaces. If distilled water is not available and tap water is used, hand-dry the instruments to remove mineral deposits from the water.
- Instrument "milk" can be used to lubricate instruments.

Ultrasonic Cleaning

Ultrasonic cleaning is a more effective cleaning method than manual cleaning. It can penetrate areas that a hand brush cannot reach. Cleaning is accomplished by the use of high frequency sound waves converted in the solution into mechanical vibrations, which pull soil out of instruments. The ultrasonic method typically removes about 90% of soil. However, it is important to recognize that it does not sterilize, or eliminate the need for initial removal of obvious blood and soil. Ultrasonic cleaning is most effective when it follows a preliminary manual cleaning to remove accessible debris from the instruments. When using an ultrasonic cleaner, always:

- Follow manufacturer's instructions carefully.
- Use the detergent solution recommended by the manufacturer.
- Strictly adhere to the cleaning times and temperatures recommended by the manufacturer.
- Use distilled water/or de-mineralized water.
- Rinse instruments with box locks open and disassembled.
- Do not overload cleaner.

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- Inspect instruments carefully on a regular basis; ultrasonic cleaning can accelerate flaking of chrome plated instruments and loosen small screws in instruments.

Sterilizing Instruments

As described above, the use of sterilized instruments is a critical requirement of sterile survival surgery techniques. All instruments used in these surgeries must be sterile. Specific sterilization methods should be selected on the basis of physical characteristics of materials to be sterilized. Sterilization indicators should be used to identify materials that have undergone proper sterilization. The use of liquid chemical sterilizing agents must be conducted in approved facilities with adequate ventilation systems and should be used with adequate contact times. Instruments should be rinsed with sterile water or saline before use. Alcohol is not a sterilizing agent.

- All articles to be sterilized must be clean.
- All articles to be sterilized should be packaged in materials (such as paper, muslin, cloth, peel packs, etc.) that protect them from contamination. The material must be porous enough to allow the penetration of the sterilizing agent (e.g. steam).
- Date (must include the sterilization date) and label the sterilized items. If multiple sterilizers are used by a laboratory group, the specific sterilizer should also be indicated on the package. The efficacy of the sterilizing process should be measured at regular intervals with a biological indicator. In addition, sterilizers should be checked at regular intervals for mechanical air removal using a product which is designed to product the challenge that is presented by a Bowie and Dick towel pack.
- Store sterilized items in a clean, dust-proof and low-humidity area. Closed storage cabinets prevent contamination more effectively. Storage under sinks or in places likely to result in wetting is to be avoided.
- Any sterilized package that is dropped or torn or has come in contact with moisture is considered contaminated and must be cleaned, repackaged and re-sterilized. All packages containing sterile items should be inspected before use to verify package integrity and dryness.
- If the package has remained intact and dry, items may be considered sterile until the time of use.