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VC – 5: SOP for Ensuring Appropriate Training of New Investigators Conducting Surgical Procedures on USDA-Covered Species

Rationale

- To establish a Standard Operating Procedure on observation of surgical procedures conducted by investigators new to Johns Hopkins University to ensure appropriate skill and technique in performing procedures on species covered by the Animal Welfare Regulations (Code of Federal Regulations, 9 C.F.R. Parts 1-4).
- Confirmation that researchers are appropriately trained to conduct surgical procedures as described in an approved animal protocol is required to ensure animal safety and well-being.
- Investigators new to Johns Hopkins University, or new to performing surgery on a particular Animal Welfare Act species, should be assessed to ensure that they can demonstrate the skill level expected of researchers in the Johns Hopkins animal program.
- All investigators proposing to conduct research with animals will be required to have submitted written documentation of training as part of the ACUC protocol review consistent with existing ACUC requirements. This observation SOP is in addition to those requirements.
- The ACUC and the Attending Veterinarian (AV) are responsible for ensuring that researchers are properly trained and qualified to perform procedures specified in approved protocols.

General Principles and Guidelines

- The ACUC and AV, by means of the ACUC approved animal protocol, determines whether the training and qualifications listed for personnel are appropriate for the surgical procedures proposed in a given species.
- The Attending Veterinarian (AV) or designee is appropriately qualified to evaluate both aseptic technique and surgical techniques, including instrument use, species-specific differences, tissue handling, and proper suture technique.
- Once confirmed to be appropriately qualified, the Principal Investigator is responsible for the training and proficiency of additional members of their lab.

Procedures

- Any of the following conditions require observation by the AV or designee to confirm that researchers are appropriately trained and qualified as described in the approved protocol:
 - A survival surgical procedure is performed for the first time at JHU by a Primary Investigator in an Animal Welfare Act species

- A survival surgical procedure is performed for the first time in a new Animal Welfare Act species
- **If on the completion of the surgical procedure, the AV or designee confirms that researchers are appropriately trained and qualified to perform all procedures as described in the approved protocol, the AV or designee may:**
 - Require observation of additional procedures before granting permission to proceed without observation.
 - Grant permission to proceed with all future surgical procedures without observation.
 - Once this permission is granted, the Principal Investigator is responsible for the training and proficiency of additional members of their lab.
- **If during or on completion of the surgical procedure, the AV or designee determines that researchers are not appropriately trained and qualified, the AV or designee has the authority to intervene in any of the following ways:**
 - Stopping the surgical procedure and either recovering or euthanizing an animal.
 - Verbal and demonstrative guidance on aseptic technique, suture technique, or other technique with approval to continue the procedure afterwards.
 - Scrubbing in to a surgical procedure to provide momentary guidance.
 - Scrubbing in to a surgical procedure to provide guidance for the remainder of the procedure.
 - Scrubbing in to a surgical procedure and completing the procedure on behalf of the researcher.
- **Any potential serious or continuing non-compliance observed will be referred to the ACUC.**

Training

- Training will be required for any portion of the surgical procedure where technique was determined to be inadequate (e.g. asepsis, suturing technique). The AV or designee will determine the amount and type of training required.
- Training will be documented using the “Research Animal Resources Surgical and Advanced Procedure Training Form”.
- Training may occur prior to the conduct of or during conduct of subsequent surgical procedures.
- The AV or designee will determine when researchers are sufficiently trained to proceed with surgical procedures without observation or assistance.