

## INSTRUCTIONS FOR COMPLETION OF THE **ACORP APPENDIX 5 – SURGERY** **(ACORP APP. 5 INSTRUCTIONS)** VERSION 4

These instructions provide detailed guidance on completing Appendix 5 of the ACORP, and are referenced to the numbers of the items in Appendix 5. ONLY complete this appendix if it is relevant to the protocol being submitted for review. The PI may use the ACORP Appendix 5 template provided in the RAMS application by using the link available in question 10 of section M.

Regulatory documents mentioned in the instructions are abbreviated as follows:

*Guide* – Guide for the Care and Use of Laboratory Animals, 8<sup>th</sup> ed., 2011  
*OLAW FAQs* – Frequently Asked Questions – PHS Policy on Humane Care and Use of Laboratory Animals (<http://grants.nih.gov/grants/olaw/faqs.htm>)  
*USDA APHIS Animal Care Policies* – Animal Care Resource Guide Policies, USDA APHIS, March 25, 2011

### General Instructions:

Answer each question by completing the table provided or entering the requested information at the ►. Enter “N/A” for any item that does not apply to this protocol. The sections of the form will expand as needed.  
To check an item, type “X” inside the ( ) provided.  
Define each abbreviation the first time it is used.

**Header for Every Page.** The header information for this appendix is pre-populated to match header for the Main Body of the ACORP to which it applies, to identify each page of this Appendix with that ACORP:

PI's last name: The PI's name is prepopulated  
Protocol No. Assigned by the IACUC – This is a unique identifier for each protocol that is automatically generated by the system to the protocol as a whole

**Official Date of Approval** – This is the date of final and unequivocal approval by the IACUC, as defined in the PHS Assurance, which determines the due dates of the first annual continuing review and the triennial *de novo* review, as applicable. The IACUC committee will enter this date into the form when a decision is made.

1. **Surgery Classification.** List as a single “surgery” all of the procedures to be performed in a single session, from induction of, to recovery from, anesthesia. If more than a single species is covered by this protocol, list the surgeries separately for each species, and identify which species will undergo each surgery.

Terminal surgery is any surgery during which the animal is euthanatized without being allowed to recover from anesthesia.

Survival surgery is any surgery after which the animal will be allowed to regain consciousness. This requires that provisions be made for recovery from anesthesia, and for post-operative care.

Major survival surgery is defined in the *Guide* (p. 117-118) as a surgical procedure in which a major body cavity is penetrated and exposed, produces substantial impairment of physical or physiological functions, or involves extensive tissue dissection or transection. Examples of major surgeries include thoracotomy, craniotomy, joint replacement, and limb amputation.

One of multiple surgeries is each survival surgery (including any minor surgical procedures that may induce substantial post-procedural pain or impairment, as well as any major surgeries) that will be performed as part of this protocol, in addition to any other such surgery (on this or another protocol) on the same individual animal. For each surgery that is one of multiple surgeries to be performed on a single animal, complete items 1.a and 1.b, below the table, to describe why it is necessary to perform the multiple surgeries on a single animal, the time interval(s) between successive surgeries, and the rationale for the time intervals indicated. The multiple surgeries may be repetitions of the same surgery, or more than one different surgery. NOTE: If an animal regulated by USDA is to undergo survival surgery on this protocol in addition to undergoing surgery on a separate unrelated research protocol, the IO may be required to submit a request to the USDA for pre-approval (*Guide*, p 30; *OLAW FAQs*, F.9; *USDA APHIS Animal Care Policies*, #14).

2. **Description of Surgeries.** Describe each surgery in enough detail for the IACUC reviewers to be able to evaluate what the effects on the animals will be. (Details about pre-operative preparation, anesthesia, and post-operative recovery will be requested in Items 5, 6, and 7, respectively, so it is sufficient to provide only summaries of these here.)
3. **Personnel.** Include any research personnel and any VMU animal care personnel who will participate in performing any of the surgeries listed in Item 1, above. Each of these individuals, and their qualifications for their roles in the surgeries should be included in Item E of the main body of the ACORP.
4. **Location of surgery.** Provide the building and room number(s) where each surgical procedure listed in Item 1, above, will be performed. In general, any survival surgical procedure should be conducted in a dedicated surgical facility or space (*Guide*, p. 116 and 118). Major survival surgery on nonrodents must be performed only in dedicated surgical facilities (*USDA APHIS Animal Care Policies*, #3). If local policy allows, survival surgery may be performed on rodents in dedicated surgical space, which may be in animal procedure rooms or laboratories (*Guide*, p. 144). For each surgery that will be conducted in space other than in a dedicated surgical facility, provide the justification below the table. NOTE: Use Appendix 9 to document each “departure” from a “should” standard in the *Guide*. Consult the IACUC or the Attending Veterinarian for help in determining whether any “departures” are involved.
5. **Pre-operative protocol.**
  - a. **Pre-operative procedures.** For each surgery listed in Item 1, above, mark each procedure that is to be performed before induction of anesthesia, to prepare the animal(s) for surgery, and enter the information requested. Medications to be administered pre-operatively will be documented separately, in Item 5.b, below.

Fast – Pre-operative fasting is standard for larger animals, but is rarely required in rodents or rabbits. If fasting is necessary for this protocol, enter the duration of the fasting period.

Withhold water – Withholding water pre-operatively is required for some procedures in some species. If it is necessary for this protocol, enter the length of time that water will be withheld.

Intravenous catheter placement -- Indicate the site(s) where any intravenous catheter(s) will be placed before surgery begins, for vascular access during surgery. Do not include here any catheters to be implanted as part of the surgery.

Other – Describe any other preparatory procedures to be performed on the animals before induction of anesthesia.

- b. **Pre-operative medications.** Include all sedatives, tranquilizers, and other agent(s) to be used for induction of anesthesia, as well as any antibiotics or other pre-treatments to be administered in preparation for surgery, regardless of whether they are administered immediately before, or over longer periods before, preparation of the surgical site on the animal. Each of these agents should also be included in Item 1 of Appendix 3.
  - c. **Pre-operative preparation of the surgical site.** Include details about hair removal (such as whether clippers or chemical hair removal products will be used, and how the clipped hair or chemicals will be cleaned away), skin disinfection, and the use of surgical drapes.
6. **Intra-operative management.** Provide details of how the animals will be maintained during surgery.

- a. **Intra-operative medications.** Include all anesthetic agents, paralyzing agents, fluids, and other pharmaceuticals that will be administered to the animal during surgery. Also include any experimental pharmaceuticals that will be administered during surgery. Each of these should also be included in Item 1 of Appendix 3.

Type “X” in the “Paralytic” column for each agent that is a neuromuscular blocking agent. Federal regulations prohibit the use of these agents for surgery unless other appropriate anesthetic agents are used to induce a surgical plane of anesthesia. Paralytics do not provide any pain relief, but animals are unable to respond physically to pain because motor control is blocked. **Very Important:** If any paralytics are to be administered, explain below the table why their use is necessary, and describe how the animals will be monitored to ensure that the depth of anesthesia is sufficient to prevent pain.

- b. **Intra-operative physical support.** Provide details about the physical support that will be provided during surgery, including information about, for example, the type of heating pads to be used, and how appropriate positioning of the animal will be maintained.
- c. **Intra-operative monitoring.** Include the variables that will be monitored (e.g., mucous membrane color, heart rate, blood pressure, motor responses), the criteria for adjusting the level of anesthesia or other support, and the additional measures that may be taken, as appropriate.

7. **Survival surgery considerations.**

- a. **Survival Period** – Enter how long the animal(s) are expected to survive after surgery (number of hours, days, weeks, etc.). For animals that will undergo multiple repetitions of any one survival surgery, enter the length of time after the last repetition before euthanasia.

Measures for Maintaining Sterility – Check each column that applies. Provide a description of any “other” measures to be taken.

- b. **Immediate post-operative support** -- List all measures that will be taken to support each animal immediately after surgery, until it recovers sufficiently from anesthesia to ambulate without danger to itself. This commonly includes the use of circulating warm water heating pads and blankets, administration of fluids, etc.
- c. **Post-operative analgesia.** Unless specifically justified to the satisfaction of the IACUC, you are obligated to routinely provide post-operative pain relief for all vertebrate animals undergoing survival surgery (*USDA APHIS Animal Care Policies, #3*; VA policy makes this applicable to rodents as well). Identify the analgesic(s) to be administered, and describe the protocol(s) of administration. Each of these should also be included in Item 1 of Appendix 3.

If post-operative analgesics will be withheld from the animals after any of the surgeries on this protocol, enter “none” in the “Agent” column for that surgery, and provide the justification for withholding analgesics, in the space below the table.

- d. Other post-operative medications. Describe the administration of any other medications (including, but not limited to, fluids, antibiotics, anti-coagulants, and other pharmacological agents) as part of post-operative care. (Each of these should also be included in Item 1 of Appendix 3.) Include as “post-operative care” all care that is specifically related to recovery from surgery.
- e. Post-operative monitoring. The experience of each of the individuals responsible for post-operative monitoring should be listed in Item E of the main body of the ACORP. (The names and after-hours contact information for these individuals must be provided to the VMU staff for use in case of any emergencies.)
  - (1) Immediate post-operative monitoring – Describe how each animal will be monitored until it recovers sufficiently from anesthesia to ambulate without danger to itself.
  - (2) Post-operative monitoring after the immediate post-operative period – Describe how each animal will continue to be monitored until it fully recovers from surgery. Include the personnel who will be responsible for the post-operative monitoring and care after-hours, and on weekends and holidays.
- f. Post-operative consequences and complications.
  - (1) Surgery may have intended consequences for the health of the animals, or may be associated with common post-operative complications. This protocol must address how each of these will be managed or treated.
  - (2) Animals may not recover as expected from surgery, so the criteria for euthanasia to prevent suffering must be specified. The endpoint criteria given here should be specific to the post-operative condition of the animals. The general endpoint criteria given in Item T of the main ACORP apply in any case.
  - (3) In case of any emergency medical situation, VMU personnel will attempt to contact research personnel on this protocol, according to the standard operating procedures of the VMU. If none of the research personnel can be reached, VMU personnel are required to provide treatment as directed by the responsible veterinarian, consistent with currently accepted standards of veterinary care and the approved ACORP, to alleviate unacceptable levels of pain or distress. Provide as much guidance as possible to allow the VMU personnel to avoid any drugs or classes of drugs that would invalidate the data that could be collected from the animal. It is understood that, if the condition of the animal is such that these agents cannot be avoided, the animal will have to be removed from the study and will be euthanatized instead.
- g. Maintenance of post-surgical medical records. The PI is responsible for ensuring that accurate, daily, post-surgical written medical records are maintained and accessible to the IACUC and to all research personnel and veterinary staff involved in the care and use of the animals on this protocol. The PI must therefore assign at least one individual (this may be the PI) to maintain the records, and must identify an accessible location where the records will be kept. Each individual involved in maintaining the records should be listed in Item E of the main body of the ACORP (Items E.1 and E.2 for research personnel, and Item E.3 for VMU staff).

8. **Certification.** The PI must sign the certification in Item Z.5 of the main body of the ACORP.