

PROTOCOL REVIEW	The IACUC must review all protocols and changes to approved protocols. [2.31, Policies #11, #12, #14]
Criteria	<p>In order to approve a protocol or significant change to an approved protocol, the IACUC must:</p> <ul style="list-style-type: none"> • review those components of the activities related to the care and use of animals, and • determine that the proposed activities meet and comply with the AWA regulations and standards
Protocol Requirements	<p>A protocol to conduct an activity involving animals must contain and comply with the requirements/assurances detailed below.</p>
General Requirements	<p>Protocols must meet the following requirements::</p> <ul style="list-style-type: none"> • provide the rationale for using animals [2.31(e)(2)] • identify the species of animals to be used [2.31(e)(1)] • justify the appropriateness of the species [2.31(e)(2)] • provide the number of animals to be used [2.31(e)(1)] • justify the number of animals to be used [2.31(e)(2)] • describe the proposed use of the animals, including final disposition of the animal [2.31(e)(3)] • contain a written assurance from the principal investigator that the proposed activities do not unnecessarily duplicate previous experiments [2.31(d)(1)(iii)] • medical care will be: [2.31(d)(1)(vii)] <ul style="list-style-type: none"> ▸ available when necessary, and ▸ provided by a qualified veterinarian • the animals' living conditions, housing, feeding, and nonmedical care will be: [2.31(d)(1)(vi)] <ul style="list-style-type: none"> ▸ appropriate ▸ in accordance with the AWA standards ▸ directed by the attending veterinarian or other qualified scientist • all personnel who will be conducting the proposed activities on the animals are qualified and trained [2.31(d)(1)(viii)] • pain/distress/discomfort are minimized [2.31(d)(1)(i) & 2.31(e)(4)]

**Painful/Distressful
Procedures**

- contain a complete description of procedures designed to assure that pain/distress/discomfort are minimized [2.31(e)(4)]
- describe the method(s) of euthanasia to be used [2.31(e)(5)]

Procedures that **may cause** more than momentary or slight pain or distress to the animal must contain **and comply** with assurances that the pain/distress is necessary and will be relieved or minimized.

Examples of procedures that can be expected to or may cause more than momentary pain or distress include, but are not limited to:
[Policy #11]

- surgery (survival or terminal)
- use of Freund's Complete Adjuvant
- ocular or skin irritancy testing
- food or water deprivation
- electrical shock, thermal stress, large doses of radiation
- paralysis or immobility in a conscious animal
- forced exercise

Protocols with procedures that may cause pain or distress must meet the following requirements:

- the principal investigator(s) has considered alternatives to the painful/distressful procedure [2.31(d)(1)(ii)]
NOTE: Refinement and reduction as well as replacement should be considered in minimizing pain and distress.
- **for electronic database searches:** a written narrative describing the methods and sources used to determine that alternatives were **not** available, including, but not limited to:
[2.31(d)(1)(ii), Policy #12]
 - ▶ date of the search
 - ▶ databases searched
 - ▶ years covered by the search
 - ▶ key words used
 - ▶ search strategy(s) used

**Surgical
Procedures**

- **for non-electronic searches:** a written narrative describing the methods and sources used to determine that alternatives were **not** available, including, but not limited to:
[2.31(d)(1)(ii), Policy #12]
 - ▶ years covered by search
 - ▶ search strategy(s) used
 - ▶ sources consulted, including, if applicable:
 - R reliable unpublished research data
 - R expert consultation (list credentials)
- painful/distressful procedures will be performed with appropriate: [2.31(d)(1)(iv)(A)]
 - ▶ sedatives
 - ▶ analgesics
 - ▶ anesthetics
- a justification for **not** using pain/distress relief which must:
[2.31(d)(1)(iv)(A)]
 - ▶ be in writing, and
 - ▶ detail the scientific reasons for withholding the relief, and
 - ▶ state the period of time (if known) that the pain/distress relief will be withheld, or
 - ▶ have an assurance statement that the pain/distress relief will be withheld for the shortest period of time necessary
- the research facility's attending veterinarian or his/her designee was consulted and involved in the planning of the procedure and pain/distress relief
[2.31(d)(1)(iv)(B)]
- paralytics (if used) will not be used without anesthesia
[2.31(d)(1)(iv)(C)]
- animals experiencing severe or chronic pain/distress that cannot be relieved will be humanely euthanized
[2.31(d)(1)(v)]

Pre- & Post-Surgical Care

Protocols that involve surgery must detail the provisions for **pre- and post-operative** care of the animals in accordance with

accepted veterinary and nursing practices, such as: [2.31(d)(1)(ix), Policy #3]

- adequate post-procedural observation and monitoring
- adequate monitoring of recovery until sternal
- placing animal in appropriate recovery or post-recovery environment

For *pain/distress-relieving drugs*, the protocol must clearly specify: [2.31(e)(4)]

- anticipated signs of pain and distress
- when drugs should be administered
- when drugs should not be administered, if required for scientific reasons
- drugs to be used
- dosages and routes of administration
- frequency of administration
- person(s) who is responsible for determining when pain-relieving drugs are needed, if appropriate

NOTE: A “PRN or as needed” order may not be sufficient to describe the appropriate use of pain/distress-relieving drugs.

Survival Surgery [2.31(d)(1)(ix)]

All survival surgery must be performed using aseptic procedures including, but not limited to:

- surgical gloves
- masks
- sterile instruments
- aseptic technique

NOTE: Surgery is survival if the animal regains consciousness during or after the operative procedure.

Non-Survival Surgery

Non-survival surgery:

- must be performed in accordance with established veterinary medical and nursing practices
- does **not** require a dedicated surgical facility

Major Operative Procedure [2.31(d)(1)(ix)]

Major operative procedures on regulated animals must be performed in a dedicated surgical facility which must be operated and maintained under aseptic procedures.

Examples of major operative procedures include, but are not limited to:

- thoracotomy
- laparotomy
- craniotomy
- thyroidectomy
- joint replacement
- amputation

Non-major Operative Procedure [2.31(d)(1)(ix)]

Non-major operative procedures on regulated animals:

- must be performed using aseptic procedures
- do **not** require a dedicated surgical facility

Examples of minor operative procedures include, but are not limited to:

- peripheral vessel cannulation
- wound suturing
- tooth extraction

Rodent Surgery [2.31(d)(1)(ix)]

Surgery on rodents:

- must be performed using aseptic procedures
- does **not** require a dedicated surgical facility

Field Site Surgery [2.31(d)(1)(ix)]

Surgeries conducted at field sites:

- must be performed using aseptic procedures
- do **not** require a dedicated surgical facility

Multiple Survival Surgeries [2.31(d)(1)(x), Policy #14]

An animal may **not** be used in more than one major operative survival procedure **UNLESS** the multiple procedures are:

- **within one protocol**, and
- justified, in writing, for scientific reasons, and
- approved by the IACUC

An animal may **not** be used **in two separate protocols** with major operative survival procedures **UNLESS**:

- approved by the IACUC, and
- an exemption is approved by the APHIS Administrator.

The request for approval of the exemption by the APHIS Administrator must: [Policy #14]

- be made by the research facility's Institutional Official
- be in writing
- contain the research facility's USDA registration number
- contain an outline of the proposal for which the procedure is requested
- specify:
 - ▶ species of animals involved
 - ▶ approximate number of animals involved
 - ▶ time frame for the proposed procedure
 - ▶ number of major operative procedures to be performed on a given animal
 - ▶ frequency of the major operative procedures
 - ▶ period of time between each major operative procedure
 - ▶ measures to be taken to ensure that pain/distress are minimized
- contain a complete scientific justification for the exemption
- contain an assurance that all other requirements of the AWA regulations and standards are met
- contain an assurance that the IACUC has approved the exemption
- be sent to the appropriate Animal Care Regional Office

	<p>NOTE: An animal that has a routine veterinary procedure, such as spaying, neutering or descenting, or an emergency major operative procedure for health reasons may be used in a protocol that requires a major survival surgery.</p>
Exceptions/ Exemptions	<p>Protocol exceptions or exemptions to a particular AWA regulation or standard must be:</p> <ul style="list-style-type: none">• justified in writing• for scientific reasons• approved by the IACUC <p>Examples of exceptions/exemptions include, but are not limited to:</p> <ul style="list-style-type: none">• use of a method of euthanasia other than one approved in the most current <i>Report of the AVMA Panel on Euthanasia</i>• continuous restraint, i.e. for over 12 hours, of a nonhuman primate• withholding of appropriate pain or distress relieving agents in a procedure that may cause more than momentary or slight pain/distress• food or water deprivation or restriction• housing an animals in smaller than required caging, such as cages in animal study areas or metabolism cages• not providing a diurnal light cycle <p>NOTE: Field studies which meet the following criteria are exempt from the regulations and do not require a written, approved exemption. The study does not: [1.1, 2.31(d)(1)]</p> <ul style="list-style-type: none">• involve an invasive procedure• harm the animals under study• materially alter the behavior of the animals under study

Pilot Studies

Protocols approved as **pilot studies** should be followed up with:

- ▶ a review of the results of the pilot study
 - ▶ re-submission of the protocol by the principal investigator, if appropriate
 - ▶ evaluation and approval/denial of the re-submitted protocol
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