

18.0 IACUC Functions

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<p>PROGRAM REVIEW</p>	<p>The IACUC must review and evaluate the research facility's program for humane care and use of animals at least once every 6 months. [2.31, Policy #29]</p>
<p>Method</p>	<p>The IACUC is responsible for determining the best method for conducting the review of the humane care and use program. [2.31(c)(3)]</p> <p>The IACUC may: [2.31(c)(3)]</p> <ul style="list-style-type: none"> • conduct a full committee review • appoint a subcommittee of at least two members to conduct the review. Note: NO IACUC member wishing to participate in the review may be excluded. • may invite an <i>ad hoc</i> consultant(s) to assist with the program review <p>The IACUC may adopt the AAALAC International Program Assessment report as its semi-annual program review if:</p> <ul style="list-style-type: none"> • the report complies with Section 2.31(c) • at least 2 members of the IACUC participated in the evaluation • no IACUC member wishing to participate was excluded • the report was signed by a majority of IACUC members • the report included any minority views
<p>Criteria</p>	<p>The review of the program of humane care and use must be based on the AWA regulations and standards (title 9, chapter I, subchapter A - Animal Welfare). [2.31(c)(1), Policy #29]</p> <p>Additional resources which may be used include, but are not limited to:</p> <ul style="list-style-type: none"> • "Guide for the Care and Use of Laboratory Animals" published by the Institute of Laboratory Animal Resources, 1996 Edition • "Guide for the Care and Use of Agricultural Animals in Agricultural Research and Teaching" published by the Federation of Animal Science Societies, 1999 Edition

Areas which should be addressed in the program of humane care and use include, but are not limited to:

- IACUC functions, such as:
 - ▶ required meetings
 - ▶ attendance at meetings, especially non-affiliated member
 - ▶ dissemination of protocols to members
 - ▶ review of humane care and use program
 - ▶ review of standard operating procedures (SOPs)
 - ▶ protocol review
 - ▶ suspended activities
 - ▶ complaint review
 - ▶ recommendations to the Institutional Official
 - ▶ reports to the Institutional Official
 - ▶ IACUC meeting minutes
 - ▶ IACUC records
- IACUC-approved departures/exceptions/exemptions, such as:
 - ▶ food/water deprivation or restriction
 - ▶ exemptions from the exercise plan for dogs
 - ▶ exemptions from the environmental enhancement plan for nonhuman primates
 - ▶ use of an animal in more than one major survival surgery
 - ▶ maintaining animals at temperatures outside the ranges specified by the standards
 - ▶ exceptions to the cleaning or sanitation requirements
 - ▶ exceptions to the diurnal lighting cycle requirement
 - ▶ exceptions to the space requirement (including innovative enclosures and metabolism cages)
- animal care, such as:
 - ▶ housing
 - ▶ environment
 - ▶ environmental enrichment for nonhuman primates
 - ▶ exercise for dogs
 - ▶ food/water
 - ▶ cleaning/sanitation

- veterinary care, such as:
 - ▶ emergency, weekend, and holiday care
 - ▶ anesthesia and surgery
 - ▶ pre/post-procedural care
 - ▶ pain/distress management
 - ▶ euthanasia
- identification
- records
- personnel issues, such as:
 - ▶ qualifications
 - ▶ training

The findings of the program review must be included in a report to the Institutional Official. [2.31(c)(3)]

<p>FACILITY INSPECTION</p>	<p>The IACUC must inspect the research facility's animal facilities at least once every 6 months. [2.31]</p>
<p>Facilities</p>	<p>Animal facilities which must be inspected include, but are not limited to:</p> <ul style="list-style-type: none"> • all sites (including remote sites) where animals are housed or used (including laboratories) • field study areas where animals are confined Note: Free range areas are not required to be inspected. • housing areas • holding areas NOTE: Animals may be held without being on a protocol but are subject to compliance with the AWA regulations and standards and IACUC inspection. • all animal study areas, including equipment, where animals are housed for more than 12 hours, such as: <ul style="list-style-type: none"> ▶ cages ▶ restraint chairs ▶ slings ▶ monitoring devices NOTE: It is strongly recommended that the IACUC inspect areas where animals are housed for less than 12 hours. • food & bedding storage areas • cage cleaning areas • surgical suites and prep areas • drug storage areas, including investigators' labs and offices, if appropriate • loading docks and transport equipment, such as: <ul style="list-style-type: none"> ▶ transport cages ▶ vehicles • housing areas at another research facility, if the IACUC is responsible for the animals housed in those areas, such as in joint studies or leasing of housing areas <p>In addition to inspecting the facilities, the IACUC should conduct:</p> <ul style="list-style-type: none"> • an assessment of the condition of the animals • an assessment of the care of the animals • a review of management practices

	<ul style="list-style-type: none"> • an assessment of animal users and caretakers ability to recognize problems of animal health and behavior • a review of the mechanism for animal users and caretakers to report animal health problems or concerns <p>Note: The IACUC should encourage employees to bring any questions, problems or concerns about the care or use of the animals to its attention.</p> <p>Animal facilities which do not need to be inspected are:</p> <ul style="list-style-type: none"> • areas used exclusively for non-regulated animals • areas containing free-living wild animals in their natural habitat • housing areas at another research facility if the IACUC has delegated responsibility for the animals housed in those areas to the other research facility's IACUC. NOTE: The IACUC should document that it has delegated the facility inspection responsibility to the other research facility's IACUC. • sites which are not in the United States or U.S. territories (foreign sites) <p>NOTE: The IACUC may choose to inspect these areas.</p>
<p>Method</p>	<p>The IACUC is responsible for determining the best method for conducting the facility inspection. [2.31(c)(3)]</p> <p>The IACUC may: [2.31(c)(3)]</p> <ul style="list-style-type: none"> • conduct a full committee inspection • appoint a subcommittee of at least two members to conduct the inspection. NOTE: NO IACUC member wishing to participate in the inspection may be excluded. • invite an <i>ad hoc</i> consultant(s) to assist with the facility inspection <p>The IACUC may adopt the AAALAC International Program Assessment report as its semi-annual program review if:</p> <ul style="list-style-type: none"> • the report complies with Section 2.31(c) • at least 2 members of the IACUC participated in the evaluation

	<ul style="list-style-type: none">• no IACUC member wishing to participate was excluded• the report was signed by a majority of IACUC members• the report included any minority views
Criteria	<p>The inspection must be based on the AWA regulations and standards (title 9, chapter I, subchapter A - Animal Welfare). [2.31(c)(2)]</p> <p>Additional resources which may be used include, but are not limited to:</p> <ul style="list-style-type: none">• “Guide for the Care and Use of Laboratory Animals” published by the Institute of Laboratory Animal Resources (ILAR), 1996 Edition• “Guide for the Care and Use of Agricultural Animals in Agricultural Research and Teaching” published by the Federation of Animal Science Societies, 1999 Edition <p>The findings of the facility inspection must be included in a report to the Institutional Official. [2.31(c)(3)]</p>

**REPORTS TO THE
INSTITUTIONAL
OFFICIAL**

The IACUC must prepare and submit reports of its program review and facility inspection to the Institutional Official. [2.31(c)(3)]

Program Review Report

The Program Review Report must: [2.31(c)(3)]

- describe how and to what extent the research facility meets the AWA regulations and standards (title 9, chapter I, subchapter A - Animal Welfare)
- describe in detail any departure from the AWA regulations and standards and include:
 - ▶ the reason for the departure
 - ▶ a classification of the departure as a significant deficiency or a minor deficiency. Note: A significant deficiency is one which is or may be a threat to the health or safety of the animal.
 - ▶ a reasonable and specific plan for correcting the deficiency
 - ▶ a schedule with dates for correcting the deficiency
- identify any IACUC-approved exemptions and variances and include:
 - ▶ a description of the exemption/variance, and
 - ▶ reason for the exemption/variance
- describe any recommendations to the Institutional Official regarding any aspect of the research facility's:
 - ▶ animal program
 - ▶ personnel
- include any minority views
- be reviewed and signed by a majority of the IACUC members

An updated Program Review Report must be submitted to the Institutional Official at least once every 6 months. [2.31(c)(3)]

NOTE: This report may be submitted separately or in combination with the Facility Inspection Report.

Facility Inspection Report	<p>The Facility Inspection Report must: [2.31(c)(3)]</p> <ul style="list-style-type: none">• describe how and to what extent the research facility meets the AWA regulations and standards (title 9, chapter I, subchapter A - Animal Welfare)• describe in detail any departure from the AWA regulations and standards and include:<ul style="list-style-type: none">▶ the reason for the departure▶ a classification of the departure as a significant deficiency or a minor deficiency. Note: A significant deficiency is one which is or may be a threat to the health or safety of the animal.▶ a reasonable and specific plan for correcting the deficiency▶ a schedule with dates for correcting the deficiency• describe any recommendations to the Institutional Official regarding the animal facilities• include any minority views• be reviewed and signed by a majority of the IACUC members <p>An updated Facility Inspection Report must be submitted to the Institutional Official at least once every 6 months. [2.31(c)(3)] NOTE: This report may be submitted separately or in combination with the Program Review Report.</p>
Uncorrected Significant Deficiency	<p>If a significant deficiency remains uncorrected due to failure to adhere to the correction plan or date, the IACUC, through the Institution Official, must: [2.31(c)(3)]</p> <ul style="list-style-type: none">• prepare a written report describing:<ul style="list-style-type: none">▶ the uncorrected deficiency▶ the reason why the deficiency was not corrected▶ the research facility's plan of action• send the written report:<ul style="list-style-type: none">▶ within 15 business days of the correction date▶ to the appropriate Animal Care Regional Office and any Federal agencies funding this activity

PROCEDURE FOR PROTOCOL REVIEW	The IACUC is responsible for the review and approval of all proposed activities related to the care and use of animals. [2.31]
Procedure	<p>A written protocol, i.e., a proposal for animal use activities, must be submitted to and approved by the IACUC prior to the start of any animal use activity.</p> <p>The IACUC must review all submitted protocols and decide to: [2.31(c)(6)]</p> <ul style="list-style-type: none">• approve the protocol, OR• require modifications in the protocol to secure approval, OR• withhold approval of the protocol <p>The IACUC review must be conducted by: [2.31(d)(2)]</p> <ul style="list-style-type: none">• the full IACUC, or• a subcommittee of at least one member of the IACUC designated by the IACUC chair who:<ul style="list-style-type: none">▸ is qualified to conduct the review, and▸ has the authority to:<ul style="list-style-type: none">□ approve□ require modifications in the protocol to secure approval, or□ request a full IACUC review of the protocol <p>Note: This person or subcommittee might be referred to as the Designated Reviewer(s) or Designated Member(s).</p> <p>Prior to IACUC review, each member of the IACUC must be provided: [2.31(d)(2)]</p> <ul style="list-style-type: none">• a list by the IACUC chair or his/her designee of the protocols to be reviewed• upon request, a copy of any protocol <p>NOTE: Any member of the IACUC may request</p>

and must be granted a full IACUC review of a protocol.

NO member of the IACUC or subcommittee may grant approval of a protocol UNTIL the entire IACUC has been informed that the protocol is to be reviewed and members are given the opportunity to read the protocol.

If an IACUC member has a conflicting interest with a protocol being reviewed, e.g., is personally involved, that member may **NOT**: [2.31(d)(2)]

- contribute to the constitution of a quorum
 - participate in the review or approval of the protocol
- NOTE: The member may provide information about the activity proposed in the protocol.

Full Committee Review

If a protocol is reviewed by the full IACUC: [2.31(d)(2)]

- the review must be conducted at a convened meeting with a quorum of the IACUC, AND
- approval must be by a majority vote of the quorum present

Subcommittee Review (Designated Reviewer)

The Designated Reviewer(s) has the authority to:

- approve a protocol
- approve a significant change(s) to a protocol
- require modifications to a protocol/significant changes
- request a full IACUC review

A protocol or significant change approved by the Designated Reviewer does **not** need to be reviewed and approved by the full IACUC.

NOTE: Only after all members of the IACUC have decided that a full committee review of a protocol is not necessary, can the protocol be reviewed by the Designated Reviewer.

Consultants	<p>The IACUC may confer with a consultant(s) or the principal investigator(s) to aid in understanding complex areas of a protocol. [2.31(d)(3)]</p>
	<p>Unless the consultant is a member of the IACUC, he/she must NOT: [2.31(d)(3)]</p> <ul style="list-style-type: none">• approve or withhold approval of a protocol• vote with the IACUC
Notification	<p>The IACUC must notify in writing the principal investigator(s) and the appropriate person(s) at the research facility (usually the Institutional Official or his/her designee) of its decision regarding the approval of the protocol. [2.31(d)(4)]</p>
	<p>If the IACUC decides to withhold approval or require modifications in the protocol, it must: [2.31(d)(4)]</p> <ul style="list-style-type: none">• include in its written notification the reason for the decision• give the principal investigator(s) an opportunity to respond in person or in writing
	<p>The IACUC may reconsider its decision to withhold approval if the principal investigator corrects the deficiencies in the protocol to the IACUC's satisfaction. Any change in the IACUC's decision must be documented in the minutes. [2.31(d)(4)]</p>
Annual Review	<p>The IACUC must review all active protocols at least once a year or more often, at the discretion of the IACUC. [2.31(d)(5)]</p>
	<p>The annual reviews should be documented in writing.</p>
Changes in Protocols	<p>The principal investigator(s) must inform the IACUC of any proposed significant changes to an approved protocol prior to the changes being implemented.</p>
	<p>The IACUC or a designated subcommittee must review and approve these changes. [2.31(c)(7)]</p>

Non-IACUC Review

Examples of significant changes include, but are not limited to:

- increase or decrease in the number of animals
- addition of a new species
- new procedure or change in a procedure being used
- change in pain classification of the procedure
- major/critical change in post-procedural pain management
- change from terminal to survival surgery
- change in personnel conducting the procedures

NOTE: If a proposed change to a protocol is minor, it may be handled administratively or at the annual review.

IACUC-approved protocols and IACUC-approved significant changes may be further reviewed and approved by officials of the research facility, such as: [2.31(d)(8)]

- the Institutional Official
- the Department Head
- Grants and Funding Committee
- Safety Committee
- Radiation Safety Committee

HOWEVER, these officials may NOT approve a protocol or significant change that has not been approved by the IACUC. [2.31(d)(8)]

NOTE: The research facility may have an internal policy requiring further approval of a protocol or significant change by a non-IACUC official for the protocol or significant change to be implemented BUT this is an internal issue, not an AWA/Animal Care issue.

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
<p>Protocol Requirements</p> <p>General Requirements</p>	<p>A protocol to conduct an activity involving animals must contain and comply with the requirements/assurances detailed below.</p> <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 approximate 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

- **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:
 - reliable unpublished research data
 - 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)]

**Surgical
Procedures**

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” frequency of administration is not acceptable unless there are detailed instructions and criteria for determining administration of the drug.

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**

NOTE: An animal that has a routine veterinary procedure, such as

**Exceptions/
Exemptions**

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.

Protocol exceptions or exemptions to a particular AWA regulation or standard must be:

- justified in writing
- for scientific reasons
- approved by the IACUC

Examples of exceptions/exemptions include, but are not limited to:

- use of a method of euthanasia other than one approved in the most current *Report of the AVMA Panel on Euthanasia*
- continuous restraint, i.e. for over 12 hours, of a nonhuman primate
- use of an animal in more than one protocol involving a major operative procedure from which it is allowed to recover
- food or water deprivation or restriction (i.e. inadequate nutrition and/or feeding less than once a day and/or watering less than twice a day for an hour each time)
- maintaining animals at temperatures outside the ranges specified in the standards
- housing an animals in smaller than required caging, such as cages in animal study areas or metabolism cages
- failure to clean and/or sanitize at required frequency
- failure to provide a diurnal light cycle
- exceptions from the exercise plan for dogs
- exceptions from the psychological well-being plan for nonhuman primates

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)]

- 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

SUSPENSION OF A PROTOCOL ACTIVITY	The IACUC may suspend a previously-approved protocol activity. [2.31]
Criteria	<p>The IACUC may suspend an activity that it previously approved if it determines that the activity is not being conducted as: [2.31(d)(6)]</p> <ul style="list-style-type: none">• described by the principal investigator, AND• approved by the IACUC <p>The IACUC may suspend an activity only: [2.31(d)(6)]</p> <ul style="list-style-type: none">• after review of the matter at a convened meeting, and• if a quorum of the IACUC is present, and• with a vote for suspension by a majority of the quorum present <p>If the IACUC suspends an activity involving animals, the Institutional Official, in consultation with the IACUC, must: [2.31(d)(7)]</p> <ul style="list-style-type: none">• review the reasons for the suspension• take appropriate corrective action• report that action with a full explanation to:<ul style="list-style-type: none">▶ the appropriate Animal Care Regional Office, and▶ any Federal agency funding that activity

OTHER FUNCTIONS	The IACUC is responsible for other activities related to animals at the research facility. [2.31, 2.32]
Concerns/Complaints	<p>The IACUC is responsible for reviewing and, if warranted, investigating concerns/complaints involving the care and use of animals at the research facility, such as: [2.31(c)(4)]</p> <ul style="list-style-type: none"> • inadequate pain relief • inadequate veterinary care • animal use activities not approved by the IACUC • use of stolen animals <p>Sources of these concerns/complaints may include, but are not limited to:</p> <ul style="list-style-type: none"> • general public • animal protection groups • laboratory or research facility personnel or employees • city, county, or State agency • APHIS personnel • another Federal agency <p>The IACUC should develop a mechanism for handling these concerns or complaints.</p>
Reprisal Allegations	<p>The IACUC is responsible for investigating any allegation of discrimination or reprisal for reporting violations to the AWA regulations and standards by a: [2.32(c)(4)]</p> <ul style="list-style-type: none"> • facility employee • IACUC member • laboratory personnel
Recommendations	<p>The IACUC is responsible for making recommendations to the Institutional Official regarding any aspect of the research facility's: [2.31(c)(5)]</p> <ul style="list-style-type: none"> • animal program • animal facilities • personnel training

**Animal Use Activity
Monitoring**

The IACUC is responsible for the appropriate monitoring of animal use activity at the research facility to: [2.31(d)(5)]

- detect deviations from the AWA regulations and standards
- ensure proper care and use of the animals
- ensure investigator compliance with the IACUC-approved protocol
- detect changes not approved by the IACUC in protocol animal use activities
- detect any non-IACUC-approved use of animals

ELECTRONIC COMMUNICATION	Some forms of electronic communication systems may be used to conduct IACUC functions. [2.31(d)(2)]
IACUC Meetings	<p>IACUC meetings must allow members to be in direct communication to consider, deliberate, and vote on areas of their responsibility. This is traditionally done by face-to-face meetings.</p> <p>The IACUC may conduct its activities using electronic communication systems which allow all members to be in direct communication, if all of the following criteria are met:</p> <ul style="list-style-type: none">• all members are given notice of the meeting• documents normally provided to members during a physically-convened meeting are provided to all members in advance of the meeting• all members have access to the documents and the technology necessary to fully participate• a quorum of voting members is convened when required• the communication system allows for real time verbal interaction equivalent to that occurring in a physically-convened meeting (i.e., members can actively and equally participate and there is simultaneous communication)• if a vote is called for, the vote occurs during the meeting and is taken in a manner that ensures an accurate count of the vote. Note: A mail ballot or individual phone polling cannot substitute for a convened meeting.• opinions of absent members that are transmitted by mail, telephone, fax, or e-mail may be considered by the convened IACUC members BUT may not be counted as votes or considered as part of the quorum• written minutes of the meeting are maintained as required by the AWA regulations <p>All activities conducted via electronic communication must be documented in writing and original signatures obtained when</p>

	<p>required.</p> <p>Examples of electronic communication systems include, but are not limited to:</p> <ul style="list-style-type: none">• conference calls• audio-visual conferencing <p>Fax, e-mail, and one-on-one communication via telephone are not acceptable methods for conducting IACUC functions which require a convened meeting, such as:</p> <ul style="list-style-type: none">• protocol review• approving a protocol• review and endorsement of semi-annual program review and facility inspection reports being sent to the Institutional Official• suspension of an activity
<p>Distribution of Information</p>	<p>Fax or e-mail is an acceptable method for the receipt or distribution of information by the IACUC, such as:</p> <ul style="list-style-type: none">• protocols from principal investigators• proposed changes to approved protocols from principal investigators• meeting notifications• agendas• meeting handouts• protocols/changes to protocols to IACUC members• request for a full committee review of a protocol• minutes of meetings• correspondence• reports• standard operating procedures (SOPs)