

IACUC REVIEW	All IACUC responsibilities, functions, and activities must be completely and thoroughly reviewed.
Membership	<p>You (the inspector) are responsible for conducting a complete and thorough inspection of a research facility's IACUC. Detailed below are some aids to assist you in evaluating the IACUC. However, you must use the regulations and your professional judgment to determine if an IACUC is in compliance.</p> <p>Ways to assess that the IACUC is functioning properly include, but are not limited to:</p> <ul style="list-style-type: none">• written meeting minutes• audio tapes• Program of Humane Care and Use• IACUC facility inspection reports• IACUC-related correspondence• memos/notes• e-mails and e-mail records• interviews with IACUC members• approved protocols• standard operating procedures• medical/surgical records• room temperature logs• maintenance records• cage wash water temperature certification records <p>In assessing IACUC membership, you should look for verification that: [2.31(a) & (b), Policy #15]</p> <ul style="list-style-type: none">• all required positions are filled NOTE: If a required position(s) is unfilled, there is not a properly constituted IACUC and decisions made by this IACUC are invalid.• there is documentation of appointment of members by the Chief Executive Officer (CEO)• the same person does not fill more than one required position NOTE: This is not prohibited by the AWA but you should strongly recommend that different people fill each required

	<p>position. [Policy #15]</p> <ul style="list-style-type: none">• the DVM has acceptable experience and responsibility for animal care and activities• the nonaffiliated member represents the general public, i.e., has no conflict of interest either personally or financially (see page 17.2.2)• there are no more than 3 members from one administrative unit of the research facility• IACUC members are qualified to assess the research facility's animal program, facilities and procedures• IACUC members are properly trained and instructed in areas such as:<ul style="list-style-type: none">▶ the Animal Welfare Act▶ protocol review▶ facility inspection
<p>Meetings</p>	<p>In assessing meetings, you should look for verification that: [2.31(c)]</p> <ul style="list-style-type: none">• meetings are held at least every 6 months for the program review and/or facility inspection• all members are informed of all meetings, such as:<ul style="list-style-type: none">▶ full IACUC meetings▶ subcommittee meetings▶ executive committee meetings• meetings are held at a time when all members, especially the nonaffiliated member, can attend• required members, especially the nonaffiliated member and the attending veterinarian, are in attendance at most meetings NOTE: If any required member is absent from a substantial number of meetings, the research facility may need to find a different person to fill the position.• all members have access to information distributed, e.g., if sent only over e-mail, all members must have e-mail• all members are sent information for an IACUC meeting in sufficient time prior to the meeting to be able to review the information• all members receive a list of protocols or the actual protocols to be reviewed in sufficient time to participate in the review or request a full committee review

	<ul style="list-style-type: none">• there is a mechanism for a member to request a full IACUC review of a protocol or participation in the appointed subcommittee review• if a member requests a full IACUC review of a protocol, a full IACUC review is conducted
Minutes	<p>The IACUC meeting minutes should include:</p> <ul style="list-style-type: none">• a list of members who attended and/or who did not attend• all the activities conducted by the IACUC at the meeting• substance of the deliberations of the IACUC, not just the decisions reached• any minority views• approval of the minutes (usually of the previous meeting) by the IACUC
Program of Humane Care & Use Review	<p>In assessing the program review, you should look for verification that: [2.31(c)(1) & (c)(3)]</p> <ul style="list-style-type: none">• the review is being conducted at least once every 6 months• if the IACUC adopted the AAALAC International Program Assessment report as its semi-annual program review, the following requirements were met:<ul style="list-style-type: none">▶ the report complied 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 the IACUC members▶ the report included any minority views• all members are informed of the date and time of the program review• all members are informed of the program review to be conducted by the appointed subcommittee in sufficient time to request participation• any member who wants to participate in the program review is allowed to do so• the program of humane care and use addresses all of the required areas (see Section 18.1)

- departures from the AWA are identified on the program review with:
 - ▶ a detailed description of the departure
 - ▶ the reason for the departure
 - ▶ classification of the departure as a significant deficiency or a minor deficiency
 - ▶ a plan and date(s) for correction of the deficiency
- IACUC-approved exemptions and variances are specifically identified, including:
 - ▶ a description of the exemption/variance
 - ▶ reason for the exemption/variance
- a report of the IACUC program review:
 - ▶ is completed
 - ▶ is signed by a majority of the members
 - ▶ contains any minority views
 - ▶ is sent to the Institutional Official
- any uncorrected significant deficiency was properly reported to Animal Care and other appropriate Federal agencies (see page 18.3.2)

Facility Inspection

In assessing the facility inspection, you should look for verification that: [2.31(c)(2) & (c)(3)]

- the facility inspection is being conducted at least once every 6 months
- if the IACUC adopted the AAALAC International Program Assessment report as its semi-annual facility inspection, the following requirements were met:
 - ▶ the report complied 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 the IACUC members
 - ▶ the report included any minority views
- all members are informed of the date and time of the facility inspection
- all members are informed of the facility inspection to be

- conducted by the appointed subcommittee in sufficient time to request participation
- any member who wants to participate in the facility inspection is allowed to do so
- all of the animal holding, housing, and use areas are inspected (see Section 18.2)
- departures from the AWA are identified on the facility inspection with:
 - ▶ a detailed description of the departure
 - ▶ the reason for the departure
 - ▶ classification of the departure as a significant deficiency or a minor deficiency
 - ▶ a plan and date(s) for correction of the deficiency
- a report of the IACUC facility inspection:
 - ▶ is completed
 - ▶ is signed by a majority of the members
 - ▶ contains any minority views
 - ▶ is sent to the Institutional Official
- any uncorrected significant deficiency was properly reported to Animal Care and other appropriate Federal agencies (see page 18.3.2)

**Reports to the
Institutional Official**

- In assessing the reports to the Institutional Official (IO), you should look for verification that: [2.31(c)(3) & (c)(5)]
- a report(s) is submitted at least every 6 months, after each program review and facility inspection
 - there is a description of how and to what extent the research facility meets the AWA regulations and standards, such as:
 - ▶ facility is in total compliance and description, or
 - ▶ describes each item not in compliance (deficiency)
 - departures from the AWA are contained in the report with:
 - ▶ a detailed description of the departure
 - ▶ the reason for the departure
 - ▶ classification of the departure as a significant deficiency or a minor deficiency
 - ▶ a reasonable and specific plan for correction of the deficiency
 - ▶ dates for correcting the deficiency

- IACUC-approved exemptions and variances are specifically identified, including:
 - ▶ a description of the exemption/variance
 - ▶ reason for the exemption/variance
- recommendations to the IO regarding any aspect of the facility's animal program, facilities, and personnel training are included in the report
- the report is signed by a majority of the members
- the report contains any minority views

Other reports to the Institutional Official which should be requested and reviewed include, but are not limited to:

- uncorrected significant deficiencies
- notice of suspension of a protocol

You should review:

- how the reports are sent to the Institutional Official, and
- if there is any confirmation from the IO that the reports were received

NOTE: If you have a concern that the Institutional Official is not receiving the required reports/information, you should visit with the IO.

**Protocol Activity
Suspension**

In assessing the IACUC's suspensions of protocol activities, you should look for verification that: [2.31(c)(8), (d)(6) & (d)(7)]

- the activity was reviewed and suspended at a convened meeting with a quorum of the IACUC present
- the suspension was approved by majority vote of the quorum present
- the Institutional Official, in conjunction with the IACUC:
 - ▶ reviewed the reason for the suspension
 - ▶ took appropriate corrective action
 - ▶ instituted adequate follow-up measures and monitoring of the suspended activity
 - ▶ informed the appropriate Animal Care Regional Office of the suspension
 - ▶ informed other appropriate Federal funding agencies of the suspension

Complaints/Concerns	<p>NOTE: If the reason for the protocol suspension was a noncompliance, then you should cite the noncompliance whether it has been corrected or not. If the noncompliance was corrected, you should state this in the citation. If not, follow the standard procedure for citing a noncompliance.</p>
	<p>In assessing the IACUC's responsibility for addressing complaints or concerns, you should look for verification that: [2.31(c)(4)]</p> <ul style="list-style-type: none">• adequate methods are in place for receiving complaints/concerns from sources outside the research facility• adequate, confidential methods are in place for receiving complaints/concerns from sources inside the research facility• complaints or concerns were reviewed and, if appropriate, investigated for validity• appropriate action was taken on valid complaints/concerns• any allegation of reprisal was investigated• apparent valid allegations of reprisal were reported to the appropriate research facility official and Federal agency, if appropriate <p>NOTE: If the issue in the complaint or concern was a noncompliance, then you should cite the noncompliance whether it has been corrected or not. If the noncompliance was corrected, you should state this in the citation. If not, follow the standard procedure for citing a noncompliance.</p>
Records	<p>In addition to the reports listed above, the following IACUC records must be available for review and in compliance with the AWA regulations: [2.35(a)(2)]</p> <ul style="list-style-type: none">• protocols (see Sections 6.3 and 14.4)• proposed significant changes to protocols• IACUC approval or non-approval of protocols or proposed significant changes to protocols• any other protocol-related information

