

<b>Policies &amp; Procedures Reference #:</b>	Section J.1 – J.7
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One of the basic functions of the IACUC, as specified in the USDA Regulations, is to review and, if warranted, investigate concerns involving the care and use of animals at the facility resulting from public complaints received and from reports of non-compliance received from researchers or personnel<sup>[1 & 5]</sup>. **The IACUC will strive to ensure that persons against whom complaints are alleged receive due process.**

Despite the severity of the non-compliance policy, the IACUC recognizes that the accused party is entitled to fair and just treatment and to a presumption that a reasonable explanation can be made for the appearance of non-compliance. Every effort will be made to maintain confidentiality and to protect the reputation of the accused party or any research throughout the investigation process.

### NON-COMPLIANCE WITH APPROVED PROTOCOLS, POLICIES, OR REGULATIONS (J.2)

Georgia Aquarium's Animal Care and Use Program requires that all animal usage be conducted in a humane and appropriate manner, in accordance with guidance from the Animal Welfare Act and accreditation standards. Any failure to comply with these policies and regulations jeopardizes all use of animals in research at Georgia Aquarium.

### EXAMPLES OF NON-COMPLIANCE (J.3)

Some examples of situations that may constitute non-compliance include, but are not limited to, the following:

- Use of animals without first obtaining IACUC approval or use of more animals than approved and/or failure to obtain de novo review of a protocol.
- Failure to use aseptic procedures during survival surgery on USDA-covered animals when the exception has not been approved by the IACUC.
- Neglecting or providing inadequate care for animals or failure to alleviate pain or distress.
- Using procedures not approved by the IACUC or failing to correct a previous non-compliance.
- Allowing untrained personnel to perform procedures or surgeries without direct supervision.
- Failure to inform the IACUC of an unexpected outcome that affects the welfare of animals.

### HANDLING CASES OF ALLEGED OR APPARENT NON-COMPLIANCE WITH PROTOCOLS OR GEORGIA AQUARIUM RESEARCH GUIDELINES (J.4)

The IACUC may investigate any cases of alleged or apparent non-compliance with Georgia Aquarium's Research Guidelines. This could include, but is not limited to, sending animal or enclosure samples or data, disseminating research information at conferences, and/or sharing photos or videos for the purpose of research without appropriate approvals.

The IACUC may suspend a protocol at any time if it determines that the activity is not being conducted in accordance with the protocol approved by the IACUC or not in accordance with guidance from the Animal Welfare Act, accreditation standards, or the IACUC's policies<sup>[2 & 3]</sup>.

Suspension of a protocol requires a majority vote taken at a convened IACUC meeting with a quorum of voting members attending. To ensure a swift and appropriate committee response, such called meetings may be held by teleconference.

**Exception:** The requirement for IACUC approval of suspension is waived in cases where the Compliance Officer, Chairman, or Internal Veterinarian pauses a protocol on an emergency basis.

These three entities have the authority to pause any protocol that does not follow the Animal Welfare Act, accreditation standards, or the IACUC's policies. The Internal Veterinarian is authorized to remove animals from active research due to medical concerns, treat the animals, and/or euthanize them, as part of their responsibilities to oversee the veterinary program for Georgia Aquarium's exhibit collection animals.

Any such pause will immediately be reported to the Compliance Officer and IACUC and will be the subject of a called, convened meeting with a quorum of committee members. The IACUC may additionally impose a period of suspension for some or all of an individual's ability to use animals until it is clear that the researchers or personnel and procedures have been brought into compliance with federal and aquarium policies and guidance. The individuals involved may be subject to further disciplinary action by this institution.

### The Process of Inquiry (J.4.1)

#### Inquiry Defined (J.4.1)(a)

An inquiry is defined as *information-gathering and preliminary fact-finding* to determine whether the potential non-compliance warrants an investigation.

#### Procedures to Be Followed When Conducting an Inquiry (J.4.1)(b)

Once advised of an alleged non-compliance matter, the Compliance Officer or designee will conduct an inquiry. Should the inquiry result in a determination that further investigation is warranted, the Compliance Officer or designee will:

- Notify the accused party, the Principal Investigator (if not the accused party), and the IACUC in writing that an allegation of non-compliance has been made. Specific deviations/claims are cited, and the accused party and Principal Investigator are instructed to adhere to the approved protocol until otherwise instructed by the IACUC or Internal Veterinarian.
- A copy of this letter /notification is sent to the Institutional Official and the accused party's supervisor (if they are Georgia Aquarium personnel).
- Call a meeting of the IACUC as quickly as possible to conduct an investigation of the alleged non-compliance.

#### Notification of Governing Authorities for an Inquiry (J.4.1)(c)

Following completion of the inquiry, the Institutional Official will advise the USDA/APHIS, if deemed necessary.

### The Process of Investigation (J.4.2)

#### Investigation Defined (J.4.2)(a)

An investigation is defined as *a formal examination and evaluation of relevant facts to determine whether non-compliance has taken place or, if non-compliance has already been confirmed, to assess its extent and consequences and determine appropriate action.*

#### Procedures to Be Followed When Conducting an Investigation (J.4.2)(b)

The alleged party and Principal Investigator (if not the alleged party) will be asked to meet with the IACUC in a called meeting to respond to the allegations. Other individuals may be asked to provide additional information. Animal care records and other documents related to the protocol may be reviewed by the IACUC.

Once the IACUC has completed the investigation and made a determination, the alleged party and Principal Investigator (if not the alleged party) will be advised in writing, with copies to the Institutional Official, the Principal Investigator (if not the alleged party), and the alleged party's supervisor (if they are Georgia Aquarium personnel).

In the event of a finding of non-compliance, sanctions imposed by the IACUC will be stated, and the notice will include guidance on the appeal process.

#### Notification of Governing Authorities for an Investigation (J.4.2)(c)

Following completion of the investigation, the Institutional Official will advise USDA/APHIS, if necessary, in cases where:

1. The protocol is suspended.
2. A determination is made that there has been serious or continuing non-compliance.
3. It is determined that there have been serious deviations from the provisions of the Animal Welfare Act.

### POSSIBLE CONSEQUENCES OF A FINDING OF NON-COMPLIANCE (J.5)

Depending on the seriousness of the non-compliance, the IACUC may do the following actions:

#### Formal Warning Letter (J.5.1)

A formal warning will be provided by the Chairman to the individual who committed the infraction. This warning will be sent in connection with a quick meeting between the Chairman and the impacted individual(s) to brief them of the situation prior to the letter's issuance. These individuals are responsible for ensuring the responsible party/team implement the corrective action(s) required by the Committee. Formal warning letters are not eligible for appeals or additional reviews by the Institutional Official.

### Appeal of a Formal Warning Letter (J.5.1)(a)

If the Committee determines to issue a formal warning letter, the responsible party and/or the individuals noted to be in non-compliance are **not** eligible to appeal the Committee's decision.

### Veto by the Institutional Official for a Formal Warning Letter (J.5.1)(b)

Formal warnings of non-compliance are **not** eligible for an additional review and final determination by the Institutional Official.

### General Sanction (J.5.2)

Failure to respond to the formal warning or the level of non-compliance warrants, will result in a general sanction<sup>[6]</sup>. Sanctions will be issued by the Chairman to the individual who committed the infraction and any applicable supervisors. The individuals noted to be in non-compliance and any other personnel deemed necessary by the IACUC will be required to discuss the deficiencies and lack of corrective action with the Chairman and Compliance Officer within **two weeks** of letter issuance.

### Appeal of a General Sanction (J.5.2)(b)

If the Committee determines to issue a general sanction letter, the responsible party and/or the individuals noted to be in non-compliance are **not** eligible to appeal the Committee's decision.

### Veto by the Institutional Official for a General Sanction (J.5.2)(b)

General sanctions for non-compliance are **not** eligible for an additional review and final determination by the Institutional Official.

### Reformative Sanction (J.5.3)

Failure to appear at a general sanction meeting, if the level of non-compliance warrants, and/or subsequent offenses of the same individual/team for the same regulation or policy, will result in a reformative sanction. The Committee will review all pertinent information and decide the appropriate remedial measures for the situation. Remedial measures can include required additional training, meeting with the Institutional Official, termination of researcher animal use privileges, and/or recommendations to the organization for disciplinary action.

Committee must obtain a quorum vote on all reformative sanctions being recommended and/or applied to individuals/teams. Reformative sanctions must also be reported by the Committee to the Institutional Official. For sanctions on activities in which there is an immediate threat to the health or safety of an animal, the Chairman may impose a reformative sanction pending rapid review by the IACUC<sup>[8]</sup>.

### Appeal of a Reformative Sanction (J.5.3)(a)

If a reformative sanction is issued to a responsible party, the responsible party has the right to submit an appeal to the IACUC in writing within **15 days** of the decision letter being sent to them<sup>[4 & 10]</sup>.

The Committee will review the written justification of the appeal at their next scheduled meeting and provide a final determination to the responsible party. A majority vote of the members attending the convened meeting is required to overturn a reformatory sanction.

### **Veto by the Institutional Official for a Reformatory Sanction (J.5.3)(b)**

Upon receiving notification from the Committee of the recommendations for a reformatory sanction, the Institutional Official may overturn or choose to impose additional or other sanctions that are more severe than those originally issued by the Committee. However, the Institutional Official cannot overturn the Committee's determination to suspend a protocol<sup>[11]</sup>.

### **SUSPENSION OF A PROTOCOL (J.6)**

A protocol can be paused temporarily by the Compliance Officer, Chairman, or Internal Veterinarian if there is an immediate threat to the health or safety of an animal, or one in which concerns of non-compliance were raised through USDA inspections, pending rapid review by the Committee<sup>[9]</sup>. However, a quorum vote of the Committee must occur to officially suspend a protocol for a prolonged period of time<sup>[7]</sup>. The Committee can also choose to partially (i.e., specific procedures) or fully suspend a protocol<sup>[7]</sup>. If a protocol is partially or fully suspended, the Committee will inform appropriate entities at the institution that the protocol is no longer valid.

### **Appeal of a Suspended Protocol (J.6)(a)**

If the Committee determines to partially and/or fully suspend a protocol for non-compliance, the responsible party and/or the individuals noted to be in non-compliance are **not** eligible to appeal the Committee's decision.

### **Veto by the Institutional Official for a Suspended Protocol (J.6)(b)**

Protocols that have been suspended for non-compliance are **not** eligible for an additional review and final determination by the Institutional Official.

### **STEPS FOR REINSTATEMENT OF A PROTOCOL (J.7)**

The administrator will schedule a follow-up inspection (or meeting) by at least two members of the IACUC. This subcommittee will determine whether sufficient action has been taken by the Principal Investigator to correct the cited deficiencies. The results of this inspection are submitted in writing to the Principal Investigator, Institutional Official, and the appropriate Zoological Operations or Aquatic Sustainability personnel.

Should the follow-up inspection be unsatisfactory, the IACUC will require appropriate action ranging from extension of the schedule for correcting the deficiencies to permanent suspension of the activity. This determination will be made by a quorum of the IACUC and will include consideration of the effect the deficiencies have on the welfare of the animals.