INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE GENERAL POLICIES AND PROCEDURES

Policies & Procedures Reference #:	Entire Document

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OUR MISSION (Section A)

The Institutional Animal Care and Use Committee (IACUC) at Georgia Aquarium is dedicated to the humane care and use of vertebrate and invertebrate animals (hereinafter, referred to as "animals") in activities related to research conducted on Georgia Aquarium animals or by Georgia Aquarium personnel[1, 2, & 3]. These *Policies and Procedures* are applicable to all research, teaching, training, and related activities (hereinafter referred to as "activities") involving live and/or dead animals, their samples, or their parts at this institution; Georgia Aquarium owned animals at other institutions; and/or when Georgia Aquarium personnel are involved in research activities.

REGULATORY AUTHORITIES GOVERNING ANIMAL USE (Section B)

The IACUC at Georgia Aquarium complies with U.S. Department of Agriculture's (USDA) Animal Welfare Act, the Animal Welfare Regulations, and the accreditation standards set forth by the Alliance of Marine Mammal Parks and Aquariums ("Alliance" or "AMMPA") and the Association of Zoos and Aquariums ("AZA"). The IACUC at Georgia Aquarium also complies with animal care accreditation standards set forth by the Association of Zoos and Aquariums (AZA).

U.S. Department of Agriculture (USDA) (B.1)

The USDA, through its division of the Animal and Plant Health Inspection Service (APHIS), administered the 1966 Animal Welfare Act and its amendments, codified at 7 USC §2131 et. seq. and CFR Title 9. The Animal Welfare Act regulates the transportation, purchase, care and treatment of animals used for exhibition, sold as pets, or used in basic and biomedical research, education and product safety testing. The Animal Welfare Act specifically applies to the use of any live or dead warm-blooded animal at the aquarium or satellite facilities. However, Georgia Aquarium believes that all animals should receive the same level of care and oversight related to research. Therefore, all animals regardless of taxa are overseen by the IACUC at Georgia Aquarium.

The Animal Welfare Act requires the establishment of an IACUC at Class R Research Facilities to review all activities using animals to ensure their humane use in research activities and to conduct semiannual assessments of the institution's animal care and use program, including inspections of all animal study areas and facilities. As a research facility, Georgia Aquarium is subject to random inspections by the USDA and files an annual report with USDA concerning its animal care and use program.

ADMINISTRATIVE ORGANIZATION OF GEORGIA AQUARIUM'S ANIMAL CARE AND USE COMMITTEE (Section C)

This section was left blank on purpose. For internal review only.

IACUC MEMBER RESPONSIBILITIES (Section D)

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MEETINGS (E.1)

The IACUC generally meets quarterly on the fourth Monday or Tuesday of the month, depending on the holiday schedule and whether there are matters to consider[5]. Additional meetings will be called if necessary for the Committee to fulfill its responsibilities. These special meetings can be called by the Chairman, Compliance Officer, or Institutional Official.

[...]

Use of Telecommunications for Meetings (E.1.1)

This section was left blank on purpose. For internal review only.

Quorum Defined (E.1.2)

A quorum constitutes a majority (more than 50%) of the current voting members of the IACUC. If a quorum is lost at any time during the meeting, no further formal action will be taken until a quorum is attained[5]. Any member who has a Conflict of Interest in a matter under consideration by the IACUC cannot be used to constitute a quorum for that portion of the meeting[1 & 4].

Meeting Recordings (E.1.3)

All IACUC meetings, regardless of their purpose (such as general business, investigations, or special reviews), are recorded primarily to support accurate note-taking. In most cases, these recordings are deleted once the official meeting notes have been finalized. However, under certain circumstances, such as during investigations, recordings may be retained by the IACUC. By participating in an IACUC meeting, all attendees acknowledge and accept that the meeting may be recorded and waive any right to challenge the admissibility of such recordings in a court of law.

Sections E.2, E.3, and E.4 were left blank on purpose. For internal review only.

WHEN AND HOW TO SECURE IACUC APPROVAL (Section F)

See the IACUC's "Projects Requiring IACUC Approval" and/or "Completing an Application" Policies, posted separately.

TYPES OF REVIEWS (G.1)

Upon receipt of the application (new protocols, annual continuing review, three-year renewals, and amendments), the IACUC follows this process:

Administrative Pre-Screening Process (G.1.1)

Protocol applications that are received by the IACUC Administration Team will be assigned an IACUC reference number (GAI-YY-##) and logged into the Protocol Tracker by the IACUC Administration Team (hereinafter, "the administrator") within **one week**.

The administrator verifies that all sections and appropriate documents have been completed and provided and verifies the completion of appropriate training for each named member of the research team[14].

After the protocol application has undergone this administrative pre-screening, it is returned to the Principal Investigator for revisions or other responses, if required[26]. The Principal Investigator will have **30 days** to return any necessary information or their request will be considered closed[21].

Regulatory Review Process (G.1.2)

Following the administrative pre-screening, protocols will be forwarded to the IACUC Compliance Officer who will conduct a regulatory review. The purpose of this review is to ensure that the application is both administratively and scientifically as completed as possible. After the protocol application has undergone this regulatory review process, it is returned to the Principal Investigator for revisions or other responses, if required[26]. The Principal Investigator will have **30 days** to return any necessary information or their request will be considered closed[21].

For Level 1 applications, this regulatory review will be the end of the processing requirements for such applications and the IACUC Compliance Officer will determine if approval, modifications, or elevation to Full Committee Review is appropriate. For Level 2 applications, they will continue through the processing procedures as described below.

Full Committee Review (G.1.3)

Following the regulatory review process, Level 2 and/or elevated Level 1 protocols will be held until the next submission cycle ends. From there, the Administration Team will send out a list of these protocols that the Committee needs to review and prepare for by the next scheduled Full Committee Review (FCR). All Principal Investigators are expected to be available, either via telephone or in-person, during the meeting time in which the IACUC is reviewing and discussing their protocol.

Principal Investigators may be called upon to provide additional information, answer questions, provide clarification, and other necessary resources to the IACUC to aid in their decision to give approval or withhold until modifications are provided.

The IACUC's determination or a processing status update is communicated an official letter, signed by the Chair, in an email to the Principal Investigator within **48 hours** after the meeting. When circumstances warrant, the Chair, Internal Veterinarian, or Administrator may call or meet with the Principal Investigator to discuss a review. Any minority opinions brought forward by a member will be documented in the meeting minutes and a copy will be saved in the protocol's file[22].

PROTOCOL REVIEW CRITERIA (G.2)

See the IACUC's "Completing an Application" Policy, posted separately.

TYPES OF DETERMINATIONS (G.3)

Upon reviewing a new protocol, amendment, and/or de novo submission request, the Committee can make one of the following determinations[1 & 19]:

Approved (G.3.1)

The proposed work is approved as presented with no modifications required. The Chairman will issue an IACUC approval letter to the Principal Investigator within 48 hours of approval, which are valid for three years from the date of approval.

Appeal of Protocol Approval (G.3.1)(a)

Only Committee members may appeal the approval of a protocol by requesting a re-call (see "Post Approval Monitoring" policy).

Veto by the Institutional Official for a Protocol Approval (G.3.1)(b)

If the Institutional Official disagrees with the Committee's approval of a protocol, they can overturn this determination by notifying the Chairman and Compliance Officer in writing of such decision and detailed justification.

Proposed activities and proposed significant changes in ongoing activities that have been approved by the IACUC may be subject to further appropriate review and approval by officials of the research facility[15].

Request for Modifications (G.3.2)

If the Committee requires additional information and/or clarification prior to making a final determination, they may submit a "Request for Modification" to the Principal Investigator. The modifications request must be fulfilled prior to the Committee resuming its review of the request. Requests in which modification responses are not received back to the Committee within 90 days will be considered "expired".

The Committee may also elect to issue a request for modification in tandem with **provisional approval**. This means that once the modification response has been received by the Principal Investigator, an approval letter may be issued by the Chairman without further review from the full Committee.

If provisional approval is not established at the time of the original review, then the Committee must communicate if its expectations are for the modifications response to return back to the full Committee or if the response can be reviewed under a DMR: General.

If the IACUC requires substantial additional information and/or has concerns about a submission, the Committee may elect to submit a **Request for Appearance** to the Principal Investigator. This request will establish a date and time in which the Committee would like an opportunity to discuss the protocol with the Principal Investigator.

Appeal of Request for Modifications (G.3.2)(a)

Requests for modifications are **not** eligible for appeals by any party.

Veto by the Institutional Official of Request for Modifications (G.3.2)(b)

Requests for modifications are not eligible for an additional review and final determination by the Institutional Official.

Approval Withheld (G.3.3)

If the Committee withholds approval for a request, the Principal Investigator will be notified in writing within 48 hours of the Committee's decision, including a statement of the reasons for its decision[14]. When circumstances warrant, the Chair or administrator may call the Principal Investigator to discuss the review. The IACUC may, at its discretion, obtain external review of the application by a IACUC of an equivalent institution and/or by expert consultants in the field of that research. Georgia Aquarium's IACUC, however, shall be the final authority in determining the acceptability of the protocol.

Appeal of Approval Withheld (G.3.3)(a)

If approval is withheld from a protocol, the Principal Investigator has the right to submit an appeal to the IACUC in writing within **15 days** of the decision letter being sent to them[14, 21, & 23].

The Committee will review the written justification of the appeal at their next scheduled meeting and provide a final determination to the Principal Investigator. A majority vote of the members attending the convened meeting is required to overturn a finding of approval withheld.

Veto by the Institutional Official for Approval Withheld (G.3.3)(b)

If the Committee determines to uphold its original determination of approval withheld, the Principal Investigator is **not** eligible to request a review by the Institutional Official. The Institutional Official cannot overturn a determination by the Committee to withhold approval[15].

Resubmission After Approval Withheld (G.3.3)(c)

A requestor reserves the right to resubmit a request with modifications, following the IACUC's determination to withhold approval on the original request[24].

Sections G.4 was left blank on purpose. For internal review only. Section G.5 can be viewed under the IACUC's "Post-Approval Monitoring Requirements" policy, posted separately.

POST APPROVAL MONITORING (PAM) (Section H)

See the IACUC's "Post-Approval Monitoring" policy, posted separately.

PROGRAM REVIEWS AND FACILITIES INSPECTIONS (Section I)

Georgia Aquarium's IACUC conducts facility inspections and animal use program reviews every six months in the months of April and October [1 & 3]. Inspections are scheduled in advance with the IACUC but are not announced to other personnel until the inspection and review and taking place. This is to mirror the experience of being inspected by the USDA and allows personnel to obtain experience, through practice, in being prepared and ensuring compliance at all times.

Facility inspections are done in all primary enclosures and holding spaces for all animals at any building utilized by Georgia Aquarium and on appropriate "buildings and grounds". The inspection form used during these inspections include multiple parameters to ensure Georgia Aquarium is compliant with the Animal Welfare Regulations (Part 2, Subparts C, D, G, and I and Part 3, Subparts E, F, and G)[1], accreditation standards, and/or institutional policies.

The remainder of this section was left blank on purpose. For internal review only.

REVIEW & INVESTIGATION OF NON-COMPLIANCE (Section J)

See the IACUC's "Investigations of Non-Compliance" and "Anonymous Reporting" policies, posted separately.

GLOSSARY

Acronym	Full Text
AAALAC	Association for Assessment and Accreditation of Laboratory Animal Care International
ACF	Animal Care Facility
Ag Guide	Guide for the Care & Use of Agricultural Animals in Agricultural Research & Teaching
AHS	American Humane Society (Humane Conservation Certification)
AHC	American Humane Conservation (a.k.a. AHA)
ALLIANCE	Alliance of Marine Mammal Parks & Aquariums
AMMPA	Alliance of Marine Mammal Parks & Aquariums
APHIS	Animal and Plant Health Inspection Service, USDA
AV	Attending Veterinarian
AVMA	American Veterinary Medical Association
AWA	Animal Welfare Act
AWRs	Animal Welfare Regulations
AZA	Association of Zoos and Aquariums
BEEP	Bird Environmental Enhancement Plan(s)
BLUEBOOK	Animal Welfare Act and Animal Welfare Regulations
CAP	Corrective Action Plan(s)
CFR	Code of Federal Regulations
CITI	Collaborative Institutional Training Initiative (Online Research Training Platform)
CFR	Code of Federal Regulations
CO	Compliance Office and/or Compliance Officer
COI	Conflict of Interest
CORE	(Full Application Package, Sections A-F)
DAG	Department of Agriculture (state level; specific name may vary)
DE NOVO	(Third Year Review of All Approved Protocols)
DMR	Designated Member Review (a.k.a. DMR: General)
DMR: Admin	Designated Member Review by Administration Team
DMR: Vet	Designated Member Review by Veterinarian Member
DNR	Department of Natural Resources (state level; specific name may vary)
DVM	Doctor of Veterinary Medicine
FCR	Full Committee Review
FOIA	Freedom of Information Act
GAQ / GAI	Georgia Aquarium Inc.
IACUC	Institutional Animal Care and Use Committee
IO	Institutional Official
IMATA	International Marine Animal Trainers' Association
IRB	Institutional Review Board
LOV	Letter of Variance
NCI	Non-Compliant Item
NIH	National Institutes of Health
NMFS	National Marine Fisheries Service
NOAA	National Oceanic and Atmospheric Administration
OLAW	Office of Laboratory Animal Welfare

Acronym	Full Text
OSHA	Occupational Safety and Health Administration
PAM	Post Approval Monitoring
PHS	US Public Health Service
PI	Principal Investigator
PRIM&R	Public Responsibility in Medicine & Research
RMS	Record Management System (for animal records)
RSVP	"répondez s'il vous plaît." (Provide a response)
SCAW	Scientists Center for Animal Welfare
SME	Subject Matter Expert
SSP	Species Survival Plan
USC	United States Code
USDA	U.S. Department of Agriculture
USFWS	U.S. Fish and Wildlife Service