INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE POST-APPROVAL MONITORING REQUIREMENTS

Policies & Procedures Reference #:	Section G.5; H.1 – H.8

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SPECIAL CONDITIONS ON APPROVAL LETTERS (G.5)

The IACUC may impose additional, special conditions that are protocol-specific and must be upheld in addition to the standard conditions and policies to retain IACUC support of a protocol. If the Committee requires special conditions with a protocol and/or amendment approval, such special conditions will be communicated within the protocol's approval letter.

Appeal of Special Conditions (G.5)(a)

If special conditions are applied to a protocol approval, 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[21]. The Committee will review the written justification of the appeal at their next meeting and provide a determination to the Principal Investigator. A majority vote of the members attending the convened meeting is required to overturn a special condition

Veto by the Institutional Official for Special Conditions (G.5)(b)

If the Committee determines to uphold its original determination of the special condition(s), the Principal Investigator has the right to submit a request for review by the Institutional Official to the IACUC in writing within **15 days** of the decision letter being sent to them[21]. The Institutional Official will review the written justification of the appeal and provide their decision back to the IACUC. The IACUC will then provide a final determination to the Principal Investigator.

POST-APPROVAL MONITORING (PAM) REQUIREMENTS (Section H)

As regulations governing the use of vertebrate animals in research have increased in complexity and detail over the years, so have the regulatory obligations of investigators and the IACUC. The Post Approval Monitoring (PAM) program assists the IACUC in its role in monitoring the conduct of animal-based research and, with the cooperation of the Principal Investigator, provides assurance to regulatory agencies and to the IACUC that animal research projects are performed in accordance with federal, state, local and institutional guidelines[2]. **Under most circumstances the Post Approval Monitoring Program applies to Level 2 Applications only, unless otherwise noted below.**

Site Visits (H.1)

PAM is generally conducted by the Compliance Officer. If a site visit is requested by the Compliance Officer, the administrator will typically schedule the site visit with the Principal Investigator and will describe what to expect during the visit.

However, the IACUC or other personnel conducting PAM on behalf of the IACUC (hereinafter, "observers") may inspect any procedures at any time. Observers will respect the research environment and will not interfere with the conduct of any procedures and shall wear any necessary personal protection equipment prescribed for the specific area or animal.

Observers will work with the Principal Investigator and the Zoological Operations or Aquatic Sustainability team (if necessary) to observe research activity, prepare accurate reports, provide recommendations for maintaining compliance, and provide training opportunities. During any post-approval monitoring session, the observer will compare procedures conducted with those listed in the approved protocol and any approved amendments. Documented differences between the procedures performed and those listed in the protocol will be brought to the attention of the Principal Investigator. The observer will also provide written documentation of the status of the post-approval monitoring process to the Principal Investigator and to the IACUC.

Any research activity with alleged or apparent threats to the health or safety of an animal can be temporarily paused by the Compliance Officer, Chairman, Internal Veterinarian, and Institutional Official, pending a thorough review and determination by the Committee. Pausing or suspension may also occur if concerns of non-compliance are raised through USDA inspections.

Possible Protocol Discrepancies (H.1.1)

The following is a list of some possible discrepancies with an approved protocol that an observer might note during a PAM visit:

- Change in apparent objectives of the study.
- Increase in degree of invasiveness.
- Increases in duration, frequency or number of procedures.
- Performing survival surgery when only non-survival surgery was approved.
- Performance of animal-handling or treatment procedures by personnel who are not listed in the approved protocol.
- Anesthetics, analgesics, tranquilizers, euthanasia agents antibiotics or other medications used but that are not noted in the protocol, or different from those listed in the protocol, or not used in accordance with the protocol and not prescribed by a veterinarian.

- Procedures listed in the protocol to promote animal welfare (e.g., post-op monitoring procedures) that are not being performed as approved in the protocol.
- Survival surgery that is not performed aseptically.

The following issues, while not anticipated, will raise concern if noted during the post approval monitoring visit:

- Research personnel who appear to lack the necessary training to appropriately perform procedures listed in the protocol.
- Conditions that are not safe for humans and/or animals.
- Insufficient recordkeeping , including incomplete or inconsistent documentation of procedures, animal handling times, and environmental conditions. In field settings, this may include failure to track individual animals, lack of real-time monitoring data (e.g., water temperature, oxygenation), or missing records of when animals were brought onboard and released. In on-site research, concerns may include missing procedural logs, outdated or incomplete health records, and failure to document use of materials (e.g., drugs, sutures).
- Animal misuse, mistreatment, or neglect, including any discrepancies that result in animal welfare concerns, will be taken seriously. Any instance that appears deliberate or reflects willful disregard for appropriate animal care will be immediately reported and formally investigated.

Animal Mistreatment: Physical or psychological wrongful or abusive treatment of an animal. Examples include hitting animals, taunting animals, animal neglect, or not providing food for punitive reasons.

Site Visit Follow Up (H.1.2)

The observer will provide written documentation of the status of the post-approval monitoring process to the Principal Investigator. The Principal Investigator will have an opportunity to respond to the report in writing and/or at the next IACUC meeting if they wish to do so. In most cases, issues can be readily and satisfactorily addressed by amending an existing protocol or reverting to the procedures which are already listed in the approved protocol. The administrator will follow up on any issues that require protocol modifications, orientation of new personnel, or training.

The administrator will support corrective actions by facilitating access to the required training and/or providing guidance for the revision of the protocol to bring it into current compliance. On occasion, additional monitoring sessions may be part of the follow-up to assist with proper corrective actions.

Site Visit Appeals & Recordkeeping (H.1.3)

Investigators who disagree with post-approval monitoring results and/or recommendations may appeal to the IACUC. A copy of the final compliance post-approval monitoring report shall be kept in either the protocol file or IACUC database.

Appeal of Site Visit Results (H.1.3)(a)

If a Principal Investigator disagrees with the findings from a post-approval monitoring session, the Principal Investigator has the right to submit an appeal to the IACUC in writing within **15 days** of the PAM results being sent to them[4].

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 PAM finding.

Veto by the Institutional Official for Site Visit Results (H.1.3)(b)

If the Committee determines to uphold the original results from the post-approval monitoring session, the Principal Investigator is **not** eligible to request a review by the Institutional Official.

Unanticipated Events (H.2)

Applies to Level 1 and Level 2 Applications

The IACUC must be notified of any unanticipated outcomes related to animal use. These include protocol and non-protocol disease or injury, unexpected pain, distress, or morbidity, unanticipated mortality, and any deviations from the approved protocol or from the Animal Welfare Act and associated regulations. These reporting requirements apply to any research approved by Georgia Aquarium's IACUC, regardless of the location in which the research is conducted.

In the event of unanticipated pain, distress, or morbidity, Georgia Aquarium's Attending Veterinarian must be contacted immediately. If unanticipated mortality occurs, both the IACUC Chair and Compliance Officer must be notified without delay. In all cases, the Principal Investigator is required to submit a completed **EVENT REPORT FORM** and submit it to the IACUC within **48 hours** of the occurrence.

Unanticipated events are defined as any unexpected outcomes or circumstances that negatively impact animal wellbeing or deviate from the approved protocol, institutional policies, or applicable regulations. To support clarity and compliance, the following are examples of reportable unanticipated events. This list is not exhaustive:

- Compromised animal welfare resulting from unforeseen issues with housing, containment, environmental conditions, or transport (e.g., inadequate space, ventilation, or water quality).
- Injuries or illnesses not described in the approved protocol, regardless of cause or severity.
- Interactions with non-target species, including handling, sampling, or any contact beyond incidental or approved procedures.
- Use of unapproved methods or equipment, such as alternative capture tools, restraint techniques, or extended handling durations.
- Real-time procedural changes made in response to unexpected conditions (e.g., modifying sampling protocols due to higher-than-anticipated animal numbers or environmental constraints).
- Unexpected behavioral responses or signs of pain, distress, or morbidity not anticipated in the protocol.

Even if such events appear to fall within the general intent of the approved protocol, they must still be reported if they were not explicitly described or anticipated. Investigators are encouraged to consult with the IACUC or the Attending Veterinarian if there is uncertainty about whether an event qualifies as unanticipated. Clear and timely communication is essential to maintaining compliance and upholding the highest standards of animal care and use.

Protocol Annual Report (H.3)

Principal Investigators must submit an **ANNUAL UPDATE FORM** by November 1st of each year. The purpose of the annual report is to inform the IACUC of the current status of the project and to obtain the number of animals that have been used in research for that reporting cycle. If the Compliance Officer has any questions or concerns about the information being reported in the annual report, they may initiate additional post-approval monitoring activities. Failure to submit the Annual Update Form for any project involving USDA-regulated species will result in the withdrawal of IACUC support for that project.

Note: IACUC protocols must, by federal regulation, undergo a complete *de novo* rewrite and review every three years. As such, all protocols must be closed at the end of the third year. If the work is to continue beyond the third year, an entirely new protocol - with veterinary consultation - must be submitted for IACUC approval.

Protocol Amendments (H.4)

Applies to Level 1 and Level 2 Applications

Protocol amendments must be submitted for review and approval in advance of implementation. How amendments are reviewed is dependent upon if the amendment is considered to be minor or significant[2 & 15]. Once amendments are approved, they will be added to the protocol package and the original protocol number will be extended, such as GAI-##-## (A#)[8].

Minor Amendments (H.4.1)

All minor amendments must be submitted using the **AMENDMENT FORM**[17] with the requested amendment(s) added to a copy of the approved protocol (in Word form). Minor amendments may be approved under a Regulatory Review or FCR. Any minor amendments not sent for FCR will be communicated to the Committee upon the next distribution of protocol descriptions and the next meeting agenda.

Examples of minor amendments include, but are not limited to:

- Substitution in personnel (other than the Principal Investigator)
- Small increase in the number of animals (<10%)[18]
- Additional non-surgical sample collection or non-invasive, non-surgical procedures
- Addition of drugs or treatments use to ameliorate pain or suffering from complications associated with an approved surgery/procedure
- Change to location where all or part of the study will be done, where the location category/categories remain(s) the same (e.g., *in situ*, onsite, other zoological institution, and/or non-zoological institution).

Significant Amendments (H.4.2)

All significant amendments must be submitted using the **AMENDMENT FORM**[17] with the requested amendment(s) added to a copy of the approved protocol (in Word form). Significant amendments related to Level 1 applications may be approved under a Regulatory Review or FCR. However, significant amendments related to Level 2 applications may only be approved under a FCR.

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

- Changes in the objectives of the study or drugs used (including add or withhold).
- Addition of minor or major surgery.
- Change in species used or addition of a USDA regulated species.
- From non-survival to survival surgeries/procedures and vice versa.
- Resulting in greater discomfort or in a greater degree of invasiveness.
- Species or in approximate number of animals used (> 10%); need to repeat trials[18].
- Duration, frequency, or number of procedures performed on one animal.
- Addition of procedures with the potential to cause pain or distress.
- Addition of procedures that may result in unexpected death or other complications not described in original protocol or change the endpoint to death.
- Changes that would render immune competent animals immunocompromised.
- Change to a location category (e.g., *in situ*, onsite, other zoological institution, and/or non-zoological institution) where all or part of the study will be done.
- Addition of prolonged restraint procedure.

De Novo (Third Year) Reviews (H.5)

Applies to Level 1 and Level 2 Applications

All on-going protocols must be re-submitted to the IACUC after three years **(data, specimen, or technical expertise requests are one year)** for a new review and granting of approval, with no limits to life of a protocol[1 & 5]. De novo reviews can be submitted up to two review cycles prior to the protocol's expiration date, but must be submitted on the IACUC's most current application forms. De Novo reviews must be reviewed utilizing the same, or higher, review process as original protocols (unless the scope of the project has been significantly reduced, whereby other review types are more appropriate).

De Novo protocols must be submitted to the IACUC with sufficient time to obtain continuing approval of the protocol before its expiration date. The IACUC will try to send out reminders to the Principal Investigator and research team, but it is ultimately their responsibility to stay compliant with continuing reviews.

Failure of the Principal Investigator to submit a de novo protocol and receive a continuing approval from the IACUC will result in the expiration of their protocol, in which all animal use activities must stop immediately. The Principal Investigator and all necessary personnel at the aquarium will be notified if a protocol is considered expired[6]. Once de novo reviews are approved, they will be identified and the tracked using an extension of the original protocol number, such as GAI-##-## (De Novo ####)[3].

Protocol Recalls (H.6)

Applies to Level 1 and Level 2 Applications

A "Protocol Recall" occurs when any member of the IACUC requests re-review of an approved request at a time other than continuing review, amendment, or receipt of a report of non-compliance or adverse event. Any member of the IACUC may recall an approved protocol at any time[25]. Such calls shall be communicated to the administrator and to the Chairman for placement on the next available meeting agenda.

The reason for requesting additional review must be provided in writing when the request is made. The Principal Investigator shall be informed by the administrator within 48 hours that an additional FCR has been called, and the reason for the recall shall be communicated to them.

The member who recalls a protocol shall present their concern at a convened meeting where a quorum has been established. The Principal Investigator and/or members of the research team shall be afforded the opportunity to address any such concerns at that same meeting. All other procedures governing a FCR shall be followed.

While the new review is underway, work may continue under the recalled protocol(s). The Principal Investigator will be notified in writing once the review is complete, including any required action items. These must be addressed by the deadline specified in the notification; otherwise, the protocol(s) may be suspended until the items are resolved.

Research Completed Form (H.7)

Applies to Level 1 (Observational Only) and Level 2 Applications

Following the completion of any protocol, the Principal Investigator must send a notification of project completion (Level 1 Applications, Observational Only) or submit a **RESEARCH COMPLETED FORM** (Level 2 Applications) to the IACUC within **60 days** of the protocol's completion. Failure to provide a Research Completed Form or submit/gain re-approval under a De Novo Review will result in withdrawal of IACUC support for that project upon the project's expiration date. For the purposes of this section, the IACUC defines "research completed" as the point at which no further animal use will occur under the protocol.

Georgia Aquarium's Research Guidelines (Reporting Publications and Presentations) (H.8)

Applies to Level 1 and Level 2 Applications

All protocols approved by Georgia Aquarium's IACUC must additionally comply with all guidelines outlined in **GEORGIA AQUARIUM'S RESEARCH GUIDELINES**. These guidelines include, but are not limited to, specifications on publications, presentations, and reporting.

Additionally, any publication or presentation (not exclusive to research) completed by Georgia Aquarium staff must additionally be reported using the "Report a Publication or Presentation" platform.