

Attachment A



NATIONAL MARINE FISHERIES SERVICE

***INTERIM
Assurance of Animal Care and Use
Form***

IACUC Use Only

IACUC Number: _____ **USDA Classification:** C / D / E
(Circle One)

Date Received: _____ **Initial Review Date:** _____

IACUC Training Complete:

IACUC Recommendations: Approved: Not Approved:

Withhold Approval Pending Modification

Type of Submission: New Modification

3-Year Renewal

IACUC Chair Signature: _____ **Date:** _____

Project Title:

Principal Investigator:

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All monitoring, and research projects involving marine mammals and marine turtles must be approved by the (*specify region*) Regional NMFS Institutional Animal Care and Use Committee prior to the commencement of the project. Principal Investigators (PI) are to submit the completed Assurance of Animal Care Form (hereafter Assurance Form) to the (*specify Region*) IACUC Office. Assurance forms need to be submitted for IACUC review 4 weeks prior to submitting a permit application.

Please submit the Completed Assurance Form as an electronic file in Microsoft Word to (*IACUC Coordinator or Chair – provide point of contact and email*). Please check to ensure we have received the document. **Remember that you must still sign the declaration page.** This may be done in person or you may print off the declaration page, sign it, and send it via regular mail or by fax (*provide fax number*). A specific IACUC number will be assigned to the Assurance Form. If you are unclear as to what is required to complete the Assurance Form, please contact IACUC Chair (*provide name and phone number*) or IACUC Coordinator (*provide name and phone number*).

YOUR ASSURANCE FORM WILL NOT BE APPROVED UNTIL COMPLETE.

The Assurance Form will be valid for **3 years after approval** contingent upon the IACUC receiving annual reports and that methods have not changed. As stipulated in the Animal Welfare Act, the Assurance Form may be renewed annually by the PI for a maximum of 2 renewals. You will receive an annual review form from the (*specify region*) IACUC for 2 years and on the third anniversary of this approved Assurance Form you will be notified of its termination. At this time you will need to submit a new Assurance Form for review.

A. Administrative Data

Project Title:

Department or Office:

Principal Investigator:

Mailing Address:

Telephone:

Fax:

Email:

Initial Submission

Renewal

or Modification

Funding Source: NMFS

Grant Title (if different from Project Title):

Anticipated Start Date: _____

Anticipated End Date: _____

Location Where Animals Will Be Housed or Study Site(s):

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Permits: Identify all relevant permits (Federal, State and other) necessary to conduct this project. Provide permit type(s), permit number(s), and expiration date(s). Please indicate if a permit application is pending a decision.

| Permit Type | Permit Number | Expiration Date |
|-------------|---------------|-----------------|
| | | |
| | | |
| | | |
| | | |

*The NMFS policy intends to comply with the **Animal Welfare Act (AWA)** - Title 7 of U.S. Code §2131 et. seq. and implementing regulations and adhere to the principles of the **U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training (USGP)** and follow the guidelines in the National Research Council **Guide for the Care and Use of Laboratory Animals**.*

B. Justifications

In accordance with USGP #2, “Procedures involving animals should be designed and performed with due consideration of their relevance to human or animal health, the advancement of knowledge, or the good of society.”

1. Research Goals:

- a. What are the scientific issues addressed by the research? Specifically, how will this research improve human and animal health or advance knowledge?
 - b. What are the specific goals of the animal studies described in this protocol?
2. Explain why animal studies are preferred to **non-animal alternatives** in achieving these research goals.

In accordance with the Animal Welfare Act – “...the principal investigator has provided written assurance that the activities do not unnecessarily duplicate previous experiments.”

3. Does this research **duplicate** previous experiments? YES NO

If YES, please explain why this duplication is necessary.

4. Do the animal procedures planned for this research involve **simple field observation** with no impact on either the animals or their environment?

YES NO

If YES, it is not necessary to complete the informational sections of this protocol form. Instead, fill answer the following:

- a. Use **Appendix A** to describe the study activities. Include all precautions to ensure no adverse impact on the study animals and their environment.
- b. Include species copies of any required permits.

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- c. Sign this form under Section H
- d. Submit this package to the NMFS Regional IACUC Chair

If **NO**, the remainder of this form must be completed. Proceed to the next section.

In accordance with the USGP #3, "The animal selected for a procedure should be of an appropriate species and quality and the minimum number required to obtain valid results."

- 5. List the **research species** (and stock) and describe why is the most appropriate species to use in these studies:

- 6. How many animals do you plan to use for the protocol? Please provide a justification for the numbers of animals used (e.g., statistical power, survey, etc). Complete the following table below to define the numbers(s) of animal(s) to be used in each **category and type procedure(s)**. All information must be consistent with the project plan and MMPA/ESA permit application. Use the following animal welfare categories:

Category (adapted from AWAR):

B: applies only to animals held captive in non research status (display, rehabilitation, brood stock, holding).

C: applies to little or momentary pain or discomfort.

D: applies to potential discomfort or pain which is relieved by the appropriate anesthetic or analgesic.

E: applies to discomfort of pain which is not relieved thus requires written justification and full IACUC approval and documented in the annual report to APHIS (must consider the 3 R's).

In accordance with the AWA: "The principal investigator has considered alternative to procedures that may cause than momentary or slight pain or distress to the animals, and has provided a written narrative description of the methods and sources (e.g. the Animal Welfare Information Center) used to determine that alternative were not available...."

| Species (Common Name) | Age/Sex | Category C (procedure) | Category D (procedure) | Category E (procedure) | Total # of animals needed for duration of project |
|--------------------------|---------|------------------------------|------------------------------|------------------------------|---|
| | | | | | |
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7. If you have placed any animal numbers in **category E**, you must complete the following (use **Appendix B** if additional space is necessary)
 - a. Explain why the pain or discomfort cannot be relieved and what procedure will be used to minimize discomfort.
 - b. What informational methods and resources did you use to determine that (no-animal or non-painful) alternative were not appropriate for this research?
 - i. Include the databases that were searched (include keywords used).
 - ii. Include literature citations
 - iii. Include meetings with knowledgeable individuals (name, date)
 - iv. Include other methods/resources

C. Research Procedures

1. General Procedures.

In accordance with the AWA, “Procedures that may cause more than momentary or slight pain or distress to the animals will a) be performed with appropriate sedatives, analgesics, or anesthetics unless withholding such agents is justified for scientific reasons in writing by the principal investigator and will continue for only the necessary period of time; b) involve in their planning, consultation with the attending veterinarian..., c) not include the use of paralytics without anesthesia...”

2. Anesthetics and Analgesics:

If anesthetics or analgesics are to be used, please provide the following information: procedure, anesthetic, dose and method of administration

| Procedure | Anesthetic | Dose & Method of Administration |
|-----------|------------|---------------------------------|
| | | |
| | | |
| | | |
| | | |

In accordance with AWA: “Activities that involve surgery include appropriate provision for pre-operative and post-operative care of the animal in accordance with established veterinary medical and nursing practices. All survival surgery will be performed using aseptic procedures, including surgical gloves, masks, sterile instruments, and aseptic techniques.”

3. **Surgical Procedures** – Is surgery to be performed? **YES** **NO**
 - a. If **YES**, list surgery location/room or field site:
 - b. If **YES**,
 - i. is it a terminal procedure? **YES** **NO**
 - ii. is it a survival procedure? **YES** **NO**

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- c. If **YES**, then describe the surgical procedure to be performed in Appendix B. Be sure to include the protocol to be followed to ensure asepsis.
 - d. If aseptic procedures are not to be performed, use this space below to justify why not and describe the procedure of choice.
 - e. Describe the post-operative care (both immediate and long-term).
4. **Euthanasia** - Will the animals be terminated at the end of the research?
 YES **NO**

If **YES**, provide the method of euthanasia:

Please consult NMFS Research Protocol Guidelines (TBD) for acceptable practices. (AVMA Guidelines, AAZV Guidelines, etc)

In accordance with the AWA, "Personnel conducting procedures on the species being maintained or studied will be appropriately qualified and trained in those procedures."

5. Please describe below the **training and qualifications** of yourself and other individuals who are included in this protocol. In particular, please be very specific about the hands-on training of those individuals performing procedures which may produce animal discomfort (i.e., restraint, injections, blood collection, surgery, tagging, biopsy, tooth extraction, urine, fecal, gastric, milk, semen, sample collection, euthanasia, etc.). Use Appendix C to further describe training and experience.

D. Husbandry Practices (research facility or rehabilitation facility)

If the animals are maintained at a research facility, an APHIS license is required and the facility must comply with AWA. If the animals are maintained at a rehabilitation facility, it must meet the NMFS Rehabilitation Facility Standards.

1. Will the research require holding the animals in temporary or long term captivity (this includes rehabilitation)? **YES** **NO**
2. If **YES**, describe the husbandry practices that will be used.
3. If **YES**, describe procedures for disposition of dead animals, including whether or not a necropsy will be performed.
4. Will the animals be removed from the facility? **YES** **NO**
 - a. If **YES**, for how long?
 - b. If **YES**, to where?
 - c. If **YES**, will they be returned to the facility? **YES** **NO**
 - d. If **NO**, why not?

Note - If removal will be greater than 24 hours, a variance request may be required.

E. Environmental Safety

1. Are infectious agents to be used or potential exposure? **YES** **NO**

If **YES**, the agent(s) is.....

If **YES**, is the agent infectious to humans? **YES** **NO**
2. Are chemical hazards to be used? **YES** **NO**

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If **YES**, the chemical hazard is.....

3. Are radioisotopes to be used? **YES** **NO**

If **YES**, the radioisotope is.....

4. Are other biohazards of concern like exposure to zoonotic agents?
 YES **NO**

If **YES**, the biohazard(s) is.....

Note - If any of the above questions are answered YES, all procedures must comply with NMFS Environmental Safety requirements (TBD).

F. NMFS Training on Animal Care and Use (TBD)

Have you completed the NMFS Vertebrate Animal Care and Use Training Program?

YES **NO**

If **YES**, give data of Training Program session....

If **NO**, you must complete this Training Program within 1 calendar year of the date of approval of this protocol and submit certification thereof to the Chair of the IACUC. This Program covers the composition and function of the IACUC, historical background, NMFS policy on animal care and use, animal welfare concerns, protocol submission, and occupational health and safety. Failure to complete this program within 1 calendar year could result in suspension of the project by the IACUC.

G. Occupational Health and Safety

List all the names and telephone numbers of personnel including yourself associated with this project and identified in this protocol who will work with animals or animal tissue. Check the appropriate box to indicate whether or not each individual has completed the NMFS Animal Care and Use Training Program. Also, check the appropriate box to indicate if each individual has fulfilled requirements for vaccination and/or testing.

| NMFS Animal Care and Use Training | Vaccination/Testing | Name | Phone | Email |
|--|--|------|-------|-------|
| <input type="checkbox"/> Yes <input type="checkbox"/> No | <input type="checkbox"/> Yes <input type="checkbox"/> No | | | |
| <input type="checkbox"/> Yes <input type="checkbox"/> No | <input type="checkbox"/> Yes <input type="checkbox"/> No | | | |
| <input type="checkbox"/> Yes <input type="checkbox"/> No | <input type="checkbox"/> Yes <input type="checkbox"/> No | | | |
| <input type="checkbox"/> Yes <input type="checkbox"/> No | <input type="checkbox"/> Yes <input type="checkbox"/> No | | | |
| <input type="checkbox"/> Yes <input type="checkbox"/> No | <input type="checkbox"/> Yes <input type="checkbox"/> No | | | |
| <input type="checkbox"/> Yes <input type="checkbox"/> No | <input type="checkbox"/> Yes <input type="checkbox"/> No | | | |

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H. Assurance

I attest to the accuracy and completeness of the information provided. I promise to conduct this work with animals in accordance with the protocol as approved by the NMFS IACUC under the NMFS Animal Care and Use Policy. I will not make any substantive changes in the above protocol without first obtaining the approval of the NMFS IACUC, and I will not use any procedures which are not included in this form.

Principal Investigator/Applicant: _____ **Date:** _____

I have reviewed the research protocol outlined on this form and hereby transmit it to the NMFS IACUC for review

Science Center or Office Director: _____ **Date:** _____

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Appendix A

Observational Study Description(s) from page _____

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Appendix B

Research Procedures Description(s) from page _____

Describe the animal procedures that are to be performed and the necessity in fulfilling the goals and objectives of the project. Be sure to be specific about any procedures which may impact the health and comfort of the study animals (e.g., frequency of performance of any procedures, methods of restraint, blood sample volumes, etc.). Please provide a justification for the animal numbers used.

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Appendix C

Training and Experience description(s)