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Science and Technology
NMFS Animal Care and Use Policy

NMFS Animal Care and Use Committee Standards

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SUMMARY OF REVISIONS:

1. Text revised to clarify research eligible for Institutional Animal Care and Use Committee (IACUC) reviews;
2. Seabirds included as additional taxa for coverage under NMFS’s Animal Care and Use program;
3. Text revised in multiple sections to clarify content including definitions; and
4. Deadlines revised to streamline clearance and annual reporting.

Signed _____
David Detlor Date
Acting Director, Office of Science and Technology

I. Introduction

The National Oceanic and Atmospheric Administration’s (NOAA) National Marine Fisheries Service (NMFS) conducts and supports research activities that work with and use live marine mammals, seabirds, and sea turtles. In 2007, the NMFS Science Board established a Task Team to develop policy and an implementation plan for NMFS Animal Care and Use Committees in accordance with the Animal Welfare Act (AWA) 7 U.S.C. §2131 *et. seq.*, the AWA implementing regulations in 9 C.F.R. §1.1 *et. seq.* (AWAR), the U.S. Government Principles (USGP) for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training, 50 FR 20864 (May 20, 1985), and the Marine Mammal Protection Act (MMPA) to assure those research methods used by NMFS and NMFS-funded researchers on live marine mammals and sea turtles constitute humane treatment of those animals. Additional taxa-specific guidelines are provided in the Appendix. This document is an update to the 2015 NMFS Animal

Care and Use policies and procedures and includes the addition of live seabird research within the scope of NMFS IACUC reviews.

II. Objective

The purpose of this procedural document is to establish consistent standards for NMFS Institutional Animal Care and Use Committees (IACUCs) for reviewing directed research on live marine mammals, sea turtles, and seabirds conducted by NMFS scientists within and outside the US Exclusive Economic Zone (EEZ). While enhancement activities, such as vaccination programs and rehabilitation of rescued animals do not typically require IACUC reviews, concerned researchers, including those operating under the Marine Mammal Health and Stranding Response permits, must defer to regional IACUCs for further guidance and action.

III. Guidance

The Office of Science and Technology (F/ST) oversees the NMFS IACUC programs by providing national guidance, ensuring consistent application of policies and procedures, providing an overview of the NMFS IACUC program, and submitting annual reports to NMFS leadership and interested entities. F/ST is also responsible for identifying and communicating training opportunities, addressing issues or challenges associated with IACUC reviews or implementation of new guidelines and policies, and participating in NMFS IACUC reviews if needed and appropriate. The section below describes NMFS IACUC approach and standards for undertaking reviews of NMFS research, as well as the requirements and duties of the NMFS IACUC.

A. Approach

- The program will consist of three regional NMFS IACUCs:
 1. Northeast/Southeast Science Centers' IACUC (Atlantic IACUC)
 2. Pacific Islands/Southwest Science Centers' IACUC (Pacific IACUC)
 3. Northwest/Alaska Science Centers' IACUC (Alaska IACUC)
- NMFS researchers stationed in the regional offices, Office of Protected Resources (F/PR), F/ST, or other headquarters (HQ) offices will report to the appropriate regional IACUC (the region where research is conducted) and would fall under that IACUC review authority. For international research, HQ offices can consult with any of the three regional IACUCs that are available to review the application or proposal. Science Center staff conducting international research should obtain approvals from their regional IACUC.
- As part of the IACUC review requirements, researchers will submit the Assurance of Animal Care and Use Form (AAC&UF) containing relevant protocols to the

relevant regional IACUC. For national programs, AAC&UF containing relevant protocols must be submitted to each regional IACUC. However, NMFS Science Center (hereafter, Center) personnel conducting research in multiple regions or oceans will submit all protocols within an AAC&UF to their regional IACUC.

- The Center Directors will be the Institutional Officials (IOs) for NMFS IACUCs. As IOs, they will oversee activities carried out by NMFS scientists within their Center or region. The IOs are responsible for administering the regional program for animal use and care and ensuring compliance with NMFS policies and procedures. For administrative purposes, the IOs will include Directors from both Centers.

B. Reporting

- On **November 1st** each year, NMFS Principal Investigators (PIs) will submit an annual (1-2 page) project report for the fiscal year to their respective regional IACUC. Each report must contain the following information: the number of animals used (by species, activity, date, location, and pain category) within the IACUC approved protocol, any deviations from approved protocol and reasons for the deviation, and planned activities for the next year in accordance with AWAR 9 C.F. R. §2.36.
- By **November 15** each regional IACUC chair will complete a United States Department of Agriculture (USDA) Animal Plant and Health Inspection Service (APHIS) *Research Facility Annual Summary Report* APHIS-7023 form (https://www.aphis.usda.gov/library/forms/pdf/APHIS_7023.pdf) and submit it to F/ST in accordance with APHIS requirements and specific to intrusive (invasive) research conducted on free-ranging marine mammals for the fiscal year.
- Also, annually on **November 15** each IACUC will submit a brief annual summary report to their respective Center Directors with a copy to the Director, F/ST. The report will contain information for the previous year on a) total IACUC reviews completed for the year and b) results of facilities inspections conducted (if applicable). The report should also include the APHIS 7023 form/s with documentation for all taxa research, including seabirds and sea turtles not included in the marine mammal-specific APHIS Research Facilities Annual Summary Report.
- Before **December 1**, F/ST Director will submit a synthesized annual NMFS Facilities Report to the APHIS Office Fort Collins, Colorado, in compliance with the AWAR at 9 C.F.R. § 2.31 and § 2.37 for Federal research facilities.
- The IACUC approval of AAC&UF and the Letter of Assurance will be valid for a period of **five years** and will not be applied retroactively. To the extent possible, IACUC approvals should be synchronized with the issuance of scientific research permit cycles.

C. Applicable Research for Review

NMFS directs and funds numerous research activities that are implemented by NMFS research partners and collaborators. However, research undertaken by non-NMFS researchers with no NMFS Co-Investigator (CI) will not be eligible for NMFS IACUC reviews. Research conducted within and beyond the United States EEZ will be subject to review and approval by NMFS IACUCs. The following researcher types will be eligible for NMFS IACUC reviews:

- Research conducted by a NMFS PI and scientific research permit holder.
- NMFS CI/s collaborating on research projects with non-NMFS institutions may provide a Letter of Assurance to the relevant Regional IACUC Chair if the non-NMFS PI's institution permit holder has an IACUC.
- If the non-NMFS PI's institution does not have an IACUC to review research protocols, NMFS CIs may request the relevant NMFS regional IACUC to review their application. Depending on project objectives, NMFS's role, and broader implications, the regional NMFS IOs, IACUC Chairs and/or IACUCs will have the authority to accept or decline the request for IACUC review.

D. Standard IACUC Requirements in accordance with AWA regulations in 9 C.F.R. § 2.31

- **Appointment:** The NMFS regional Center Directors will appoint regional IACUC Chairs to implement NMFS IACUC Policy and Procedures.
- **IACUC Chair Tenure:** The Chair will serve a **three-year term** with an option to extend for another three years (i.e., six years total), at the discretion of the Center Director(s). Although not mandatory, IACUC Chairs should rotate after a three or six-year term to ensure equal representation from each Science Center within an IACUC region. F/ST should be informed of any changes in IACUC composition and IACUC Chair rotations.
- **Committee Composition:** The NMFS IACUC (with voting authority) will be composed of a **minimum of three** members including the following, on a term-limited basis. In accordance with the AWA, 7 U.S.C. §2143, no more than three members shall be from the same Center/office. Also, the AWA requires the veterinary professional and non-affiliated member be two of the three members. All committee members must be federal employees, whether from NMFS/NOAA, another federal agency, or the military.
 - i. **IACUC Chair** is responsible for all administrative activities of the IACUC and reports to the IOs. The Chair is appointed by the Center Director(s) and is responsible for overseeing implementation of the IACUC in compliance with this policy, AWA, and AWA regulations. The Chair is responsible for selecting the IACUC members. This position should be held by a person with sufficient

stature (e.g., seniority or tenure) with direct access to the Center Director(s); has excellent communication, administrative, and facilitation skills; has working knowledge of IACUC policy and procedural guidelines and review process, and will be impartial and maintain the integrity of the IACUC.

- ii. **The veterinarian** has expert knowledge of IACUC procedures and practices and provides assurance that research projects involving live animals are humane and follow the best possible animal care and field practices. The veterinarian will serve a three-year term with an option to extend for another three years (i.e., six years total), at the discretion of the Center Director(s).
 - iii. **Non-affiliated member** is not affiliated with the regional NMFS Centers other than as a member of the NMFS IACUC and shall not be a member of the immediate family of a person affiliated with the regional NMFS Centers. The non-affiliated member will represent general public interests in the proper care and treatment of animals. The non-affiliated member will serve a three-year term with an option to extend for another three years (i.e., six years total) at the discretion of the Center Director(s).
 - iv. **Researcher Member** is a practicing scientist with experience in wildlife field or laboratory research, represents the research community in the review process, and aids in the IACUC's assessment of the relevance, validity, and technical aspects of the studies proposed. The Researcher member(s) will serve a three-year term with an option to extend for another three years (i.e., six years total), at the discretion of the Center Director/s.
 - v. **Alternate** members should also be designated if IACUC members cannot review and vote on specific AAC&UF due to absence or conflict of interest.
 - vi. **IACUC Coordinator (optional) is a non-voting committee member that is responsible** for coordinating the regional IACUC. The IACUC Coordinator reports directly to the IACUC Chair and provides administrative support to the IACUC by assisting investigators with protocol submissions, preparing the agenda for IACUC meetings, transcribing meeting notes and generating correspondence to send to researchers, responding to inquiries from researchers regarding NMFS policies, serving as a liaison and maintaining communication among the IACUC members and researchers, and performing other duties as required to support the IACUC. In the absence of a coordinator, the IACUC Chair or designated member will administer proceedings and coordinate meeting logistics.
- **Quorum:** If full IACUC review is requested for a proposed activity, approval of that activity may be granted only after review and approval vote at a convened meeting (in person, phone, email, or via video) of a quorum of the IACUC present.

For purposes of this Procedural Directive, a quorum represents a *simple majority* of the voting IACUC membership. Suspension of activity requires approval by the full IACUC.

- **Conflict of Interest:** No member may participate in the IACUC review or approval of an activity if there is a personal or professional conflict of interest with the activity or with the PI/s. The Chair may excuse themselves from discussions if there is a perceived professional conflict with the PI/s. However, the Chair or member could provide additional information to help clarify any questions that may arise.
- **Ad hoc consultants:** The IACUC may invite experts in specific relevant topics to assist the IACUC with protocol reviews. A consultant does not have voting rights and may not approve or withhold approval on an activity. Examples of ad hoc experts include marine mammal, seabird, and sea turtle research scientists, statisticians, animal health technicians, occupational health experts, and information resource specialists.
- **Professional guidelines:** The IACUC are encouraged to use guidelines established by professional societies (e.g., American Society of Mammologists, Society for Marine Mammalogy, American Society of Ichthyologists and Herpetologists, Ornithological Council) and the Institutional Animal Care and Use Committee Guidebook to assist with review of AAC&UFs. A list of resources is provided in the Appendix of this Procedural Directive.
- **Training:** PIs should have a basic understanding of AWA and forms to be completed for IACUC reviews. A set of regional training modules is available through regional IACUCs, and PIs or CIs should certify in the AAC&UF that they have read the relevant training modules. New training tools and materials will be developed and provided as they become available. IACUC Chairs are expected to be familiar with the AWA, AWAR, USGP, and other established wildlife research animal use and care guidelines (e.g., ASM, SMM), and try to attend at least one Scientists Center for Animal Welfare (SCAW), or other professional society-organized IACUC training workshops/sessions specific to wildlife research. In general, each IACUC member should take the equivalent of an IACUC 101 course at least once during their tenure and take additional training as directed and appropriate by F/ST and the IACUC Chairs.

E. Duties of the NMFS IACUC (AWAR, 9 C.F.R. § 2.31) (See Table 1 below for requirements)

- Review and approve the Assurance of Animal Care and Use Form (AAC&UF), require modification or withhold approval of proposal components, and assure that all animal use in research is conducted in a humane manner in accordance with the AWAR and USGP.
- Prepare Letters of Assurance for “approved protocols” valid for 5 years and transmit review decisions promptly to PI and IO.

- Assign an AAC&UF number to all applications for IACUC reviews, including field studies. This number can be cited by NMFS scientists in both peer and non-peer reviewed publications.
- Evaluate the training and experience of the research personnel.
- Facilitate the preparation and submission of the regional IACUC Annual Facilities and Summary Report to the IOs and F/ST
- Identify any deficiencies in compliance with “approved protocols” recommend corrective steps and inform the IOs if compliance issues have not been resolved.
- Investigate concerns raised by the public or research personnel about the care and use of animals.
- Make recommendations regarding animal care and use protocols, facilities, and occupational safety and training.
- Suspend an activity or entire research project involving animals if it violates IACUC “approved protocols”
- Ensure that fellow IACUC members undergo training to be effective members of the IACUC.

Table 1. Detailed duties of the NMFS IACUC as required under the AWAR, 9 C.F.R. § 2.31

<i>Duties</i>	<i>Requirements</i>
<p>Captive Animal Facility Inspection and Monitoring</p>	<ul style="list-style-type: none"> ▪ Inspect research facilities containing marine mammals every 6 months. Rescue and rehabilitation centers are not included. Inspection responsibilities cannot be delegated to non-IACUC members. Note: Sea turtles and seabirds are not USDA regulated species; sea turtle and seabird holding facilities would be inspected following USGP guidelines. ▪ AWAR 9. C.F.R. §2.31(c)(3) provides flexibility for an IACUC to determine the best means to conduct semi-annual evaluations of the animal care and use program of captive animal holding facilities, provided at least two Committee members are part of the subcommittee performing the evaluation, and no IACUC member is denied participation. Ad hoc consultants can be used in these inspections. ▪ Subcommittees consisting of a minimum of two Committee members may elect to divide into groups headed by one Committee member during an inspection, provided the IACUC determines this to be the best means to conduct the evaluation, and each Committee member is provided an opportunity to conduct inspections if requested.
<p>Protocol review and meetings</p>	<ul style="list-style-type: none"> ▪ Review of AAC&UF (protocol reviews) can be done by the full committee in person or via phone, email, webinars, or video teleconference. Minor modifications or renewals to “approved protocols” can be handled by a designated member review at the discretion of the Chair. But any IACUC member may request a full committee review of any submitted proposal or protocol. Significant changes would require a full review. ▪ Conduct regular business meetings to review IACUC programs, inspection reports (if applicable) and reports of IACUC approved research.
	<ul style="list-style-type: none"> ▪ Meeting minutes must be recorded.

<p>IACUC records management</p>	<ul style="list-style-type: none"> ▪ All IACUC reviews must include any minority views raised by IACUC members on protocol reviews. ▪ Document non-compliance of “approved protocols” and facility deficiencies and include any corrective actions. ▪ For NMFS purposes, IACUC member training certification documentation and all other records.
<p>Reporting</p>	<ul style="list-style-type: none"> ▪ The IACUC Chairs will submit the Annual Research Facility Report to F/ST by November 15 every year. F/ST will submit compiled reports to USDA-APHIS in compliance with AWAR 9 C.F.R. §2.36 before December 1 of each year. Also, by November 15 of each year, each regional IACUC will submit a brief annual summary report of IACUC reviews conducted across all taxa and include the APHIS Form 7023 to the IOs (Center Directors) with a copy to the Director, F/ST.
<p>Animal Care and Use Assurance Reviews</p>	<ul style="list-style-type: none"> ▪ IACUC reviews will assess and assure that all use of live marine mammals, seabirds, and sea turtles is conducted in a humane manner in accordance with the AWA and USGP. ▪ In addition to meeting AWA and USGP requirements (see References), IACUC reviews also will assess and assure that all use of live marine mammals is conducted in a humane manner in accordance with the MMPA to support reviews conducted by F/PR in considering whether to issue a requested MMPA or ESA permit or permit modification to conduct research or enhancement activities on marine mammals. ▪ Additional considerations for IACUC reviews based on AWAR 9 C.F.R. §2.31(d) include: (1) Adequacy of training and experience of personnel in the procedures used (per AWAR 9 C.F.R. §2.32), (2) Criteria for euthanasia if serious injury occurs as an unintended consequence of the research activity in an “approved protocol” (3) Method of euthanasia and/or disposition of animal or carcass, and (4) Safety of working environment for personnel.

	<ul style="list-style-type: none">▪ IACUC reviews may offer refinements to research (e.g., use of less-invasive procedures), and adoption of non-invasive techniques (e.g., modeling).▪ To facilitate reviews, F/ST in coordination with F/PR and regional IACUCS will develop and update a collection of standard operating procedures (SOPs) (e.g., detailed descriptions of research procedures contained in past IACUC “approved protocols”) and scientific research permit applications, especially for sea turtles and marine mammals. IACUCs will streamline reviews of applications that propose using only approved SOPs, once they are developed. Full IACUC reviews shall be conducted of detailed AAC&UFs that contain novel or more invasive techniques not contained in an approved SOP. Any committee member may call for a full committee review.▪ The IACUC Chair will address whether the research project meets the definition of observational study (AWAR “Field Study” definition). If so, then the work may be exempt from an IACUC review as decided by the NMFS IACUC Chair, but can always be called for full review by any committee member.▪ The Chair must provide information to all committee members, giving them the opportunity to review and call for full committee review before proceeding with a designated member review. Requests that might be appropriate for a designated member review are slight modifications to IACUC approved protocols, e.g., adding additional samples to be taken while an animal is restrained for sampling or adding a different instrument type or flipper tag type, none of which changes the characteristics of the animals handling in so far as pain or distress are concerned.
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IV. References

1. Animal Welfare Act (AWA) – 7U.S.C. §2131 *et. seq.*
2. Animal Welfare Act Implementing Regulations (AWAR 9 C.F.R. 1.1 *et. seq.*). Specifically, 9 C.F.R. §2.37 requires that each Federal research facility shall establish an Institutional Animal Care and Use Committee which shall have the same composition, duties, and responsibilities required of nonfederal research facilities by 9 C.F. R.§2.31 with the following exceptions:
 - a. The Committee shall report deficiencies to the Center Director (as the IO) conducting the research rather than to APHIS; and
 - b. The relevant Center Director shall be responsible for all corrective action to be taken at the facility and for granting all exceptions to inspection protocols.

Per the AWAR, IACUC reviews will assess whether procedures in AAC&UFs:

- (1) constitute humane treatment of animals as defined in the MMPA, , the requirements set forth in the AWAR at 9 C.F.R. §2.31(d), and the USGP;
 - (2) will avoid or minimize discomfort, distress, and pain;
 - (3) the PI has considered alternatives to procedures that cause more than momentary or slight pain or distress;
 - (4) do not unnecessarily duplicate previous experiments;
 - (5) provide rationale for involving animals and for the appropriateness of species and sample size used;
 - (6) the applicant has applied the “3Rs” (Replacement – use of non-animal models, Reduction of numbers of animals used, and Refinement – elimination or reduction of unnecessary pain and distress of animals);
 - (7) veterinarians are consulted in the protocol planning and medical care will be available to captive animals and provided as necessary by a qualified veterinarian; and (8) for surgery, preoperative and post-operative care is provided and operative procedures performed in the field are carried out using aseptic procedures.
3. U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training (USGP) Office of Science, Technology, and Policy (OSTP), 50 FR 20864 (May 20, 1985). Whenever U.S. Government agencies develop requirements for testing, research, or training procedures involving the use of vertebrate animals, the following principles shall be considered; and whenever these agencies perform or sponsor such research procedures, the responsible IOs shall ensure that these principles are adhered to:

- (1) The transportation, care, and use of animals should be in accordance with the Animal Welfare Act (7 U.S.C. §2131 et. seq.) and other applicable Federal laws, guidelines, and policies.
 - (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.
 - (3) The animals selected for a procedure should be of an appropriate species and quality and the minimum number required to obtain valid results. Methods such as mathematical models, computer simulation, and in vitro biological systems should be considered.
 - (4) Proper use of animals, including the avoidance or minimization of discomfort, distress, and pain when consistent with sound scientific practices, is imperative. Unless the contrary is established, investigators should consider that procedures that cause pain or distress in human beings may cause pain and distress in other animals.
 - (5) Procedures with animals that may cause more than momentary or slight pain or distress should be performed with appropriate sedation, analgesia, or anesthesia. Surgical or other painful procedures should not be performed on non-anesthetized animals paralyzed by chemical agents.
 - (6) Animals that would otherwise suffer severe or chronic pain or distress that cannot be relieved should be painlessly killed at the end of the procedure or, if appropriate, during the procedure.
 - (7) The living conditions of animals should be appropriate for their species and contribute to their health and comfort. The housing, feeding, and care of all animals used for biomedical purposes must be directed by a veterinarian or other scientist trained and experienced in the proper care, handling, and use of the species being maintained or studied.
 - (8) Investigators and other personnel shall be appropriately qualified and experienced for conducting procedures on living animals. Adequate arrangements shall be made for their in-service training, including the proper and humane care and use of laboratory animals.
 - (9) Where exceptions are required in relation to the provisions of these Principles, the decisions should not rest with the investigators directly concerned but should be made, with due regard to Principle II, by an appropriate review group such as an institutional animal care and use committee. Such exceptions should not be made solely for the purposes of teaching or demonstration.
4. Guide for the Care and Use of Laboratory Animals, Institute for Laboratory Animal Research, National Academy of Sciences, 2011.
 5. Institutional Animal Care and Use Committee Guidebook, a publication by the Applied Research Ethics National Association and the NIH Office of Laboratory Animal Welfare, 2nd Edition, 2002.

6. Guidelines for use of live amphibians and reptiles in field and laboratory research. Second edition, revised by the Herpetological Animal Care and Use Committee (HACC) of the American Society of Ichthyologists and Herpetologists, 2004.
7. N. J. Gales, W. D. Bowen, W. F. Perrin D. W. Johnston, K. M. Kovacs, C. L. Littnan, J. E. Reynolds III, and P. M. Thompson 2009. Guidelines for the treatment of marine mammals in field research. *Marine Mammal Science*, 25(3): 725–736 (DOI: 10.1111/j.1748-7692.2008.00279.x)
8. Robert S. Sikes, the Animal Care and Use Committee of the American Society of Mammalogists, 2016 Guidelines of the American Society of Mammalogists for the use of wild mammals in research and education, *Journal of Mammalogy*, Volume 97, Issue 3, 9 June 2016, Pages 663–688, <https://doi.org/10.1093/jmammal/gyw078>.
9. Fair, J., E. Paul, and J. Jones, Eds. 2010. *Guidelines to the Use of Wild Birds in Research*. Washington, D.C.: Ornithological Council.
https://birdnet.org/wp-content/uploads/2017/07/guidelines_august2010.pdf
10. Ornithological Council. 2018. *Ornithological Council Guidelines to the Use of Wild Birds in Research*, 2018 Supplement.
<https://birdnet.org/wp-content/uploads/2018/02/Drones-OCGuidelines.pdf>

V. Appendix: Links to IACUC Resources

- Animal Welfare Act, regulations, and standards from the USDA Animal and Plant Health Inspection Service (APHIS) <https://www.aphis.usda.gov/aphis/ourfocus/animalwelfare>
- U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training <https://olaw.nih.gov/policies-laws/phs-policy.htm>
- American Veterinary Medical Association's guidelines for the euthanasia of animals, 2013 edition <https://www.nps.gov/orgs/1103/upload/AVMA-2013-euthanasia.pdf>
- Animal Welfare Information Center <https://www.nal.usda.gov/awic/institutional-animal-care-and-use-committees>
- 2016 guidelines of the American Society of Mammalogists for the use of wild animals in research and education
http://www.mammalsociety.org/uploads/committee_files/CurrentGuidelines.pdf
- Ornithological Council guidelines for the use of wild birds in research
<https://birdnet.org/info-for-ornithologists/guidelines-to-the-use-of-wild-birds-in-research/>
- Guidelines for use of live reptiles and amphibians in research
<http://www.asih.org/sites/default/files/documents/resources/guidelinesherpsresearch2004.pdf>

VI. Glossary

Activity for purposes of this NMFS Policy and Procedural Directive means research tests or experiments, using live marine mammals, sea turtles, and seabirds.

Animal for purposes of this NMFS Policy and Procedural Directive means live marine mammals, sea turtles, and seabirds. The purpose of this Policy and Procedural Directive is to ensure NMFS' compliance with not only the AWA and AWAR (i.e., interpreted by APHIS to refer to warm-blooded animals), but also the USGP. Currently, this Policy Statement specifically addresses care and use of marine mammals, sea turtles, and seabirds.

Federal Agency means an Executive agency as is defined in 5 U.S.C. § 105.

Federal Award means any mechanism (including grant, award, loan, contract, or cooperative agreement) under which Federal funds are used to support the conduct of research, experimentation, or testing involving the use of animals. The permit system established under the authorities of the Endangered Species Act, the Marine Mammal Protection Act, and the Migratory Bird Treaty Act, are not considered federal awards under the Animal Welfare Act. (AWAR, 9 C.F.R. §1.1)

Federal Research Facility means each department, agency or instrumentality of the United States that uses live animals for research and experimentation. This includes any research facility which receives a Federal award for the conduct of research, experimentation, or testing involving the use of animals. (AWAR 9 C.F.R. §1.1)

Field Study means a study conducted on free-living wild animals in their natural habitat. However, this term excludes any study that involves an invasive procedure, harms, or materially alters the behavior of an animal under study. (AWAR 9 CFR §1.1)

Humane: As defined in the MMPA: *“humane means that method of taking, import, export, or other activity which involves the least possible degree of pain and suffering practicable to the animal involved”* (16 U.S.C. 1362 and 50 C.F.R. §216.3). Further, from the AWAR: *“Procedures involving animals will avoid or minimize discomfort, distress, and pain to the animals”* 9 C.F.R. § 2.31(d)(i). And from the USGP: *“Proper use of animals, including the avoidance or minimization of discomfort, distress, and pain when consistent with sound scientific practices, is imperative. Unless the contrary is established, investigators should consider that procedures that cause pain or distress in human beings may cause pain or distress in other animals.”* (in part; see Reference 3 above).

Intrusive (invasive) Research means a procedure conducted for bona fide scientific research involving: A break in or cutting of the skin or equivalent, insertion of an instrument or material into an orifice, introduction of a substance or object into the animal's immediate environment that is likely either to be ingested or to contact and directly affect animal tissues (i.e., chemical substances), or stimulus directed at animals that may have an impact on normal function or behavior (i.e., audio broadcasts directed at animals that may have the potential to injure an animal

in the wild, equivalent to Level A harassment defined under the MMPA). (Based on MMPA regs at 50 C.F.R. §216.3). This definition is applicable to marine mammals, sea turtles, and seabirds.

NMFS Scientist/Researcher Under this NMFS Procedural Directive and Policy Statement means any NMFS employee who uses or proposes to use live marine mammal, seabird or sea turtle subjects or use of any NMFS facilities or platforms for the purpose of carrying out research, testing, or experiments using live animal subjects.

Principal Investigator (PI) means an employee of a research facility or other person associated with a research facility, responsible for a proposal to conduct research and for the design and implementation of research involving animals. (AWAR 9 C.F.R. §1.1)

PI also means the individual primarily responsible for the taking, importation, export, and any related activities conducted under a permit issued for scientific research or enhancement. The PI must have qualifications, knowledge, and experience relevant to the type of research activities authorized by the permit. (MMPA regs at 50 C.F.R. §216.3)

Co-Investigator (CI) means the on-site representative of a PI. This person has qualifications comparable to the PI and is authorized to conduct or directly supervise the conduct of the taking, import, and export activities authorized under a permit. There can be numerous CIs designated under a single permit. For example, there could be separate CIs in charge of distinct activities or projects under a single permit, or responsible for distinct geographic areas under a permit. (MMPA regs at 50 C.F.R. §216.3). The CI can also be associated with a project involving a non-NMFS scientist or researcher or institution and may not be the primary permit holder.

Marine Mammal Protection Act Scientific Research Permits (MMPA Permits) means any permit issued under the MMPA, which identify the number and kind of animals that are authorized to be taken or imported; the location and manner in which they may be taken, or from where they may be imported; the period during which the permit is valid; and any other terms or conditions the Secretary deems appropriate. (16 U.S.C. §1362)

Observational Research is research on animals in their natural habitat that does not involve invasive procedures, harm, or materially alter the behavior of an animal under study (i.e., considered to meet AWAR definition of field study (AWAR 9 C.F.R. §1.1) and exempted from full IACUC review per AWAR 9 C.F.R. §2.31(d)(1)) and may include the following:

- **For Marine Mammals:** research activities that may qualify as observational research include photo-identification studies, behavioral observations, passive acoustics, and vessel and aerial population surveys. (MMPA regs at 50 C.F.R. §216.45 (a)(3))
- **For Sea Turtles:** research activities that may qualify as observational research include behavioral observations and vessel and aerial population surveys.
- **For Seabirds:** research activities that may qualify as observational research include behavioral studies and some aerial population and monitoring surveys.

Although observational field studies are exempt from review, NMFS IACUCs are required to review all proposed marine mammal, sea turtle, and seabird field studies. The IACUC Chair, designated member or full committee can approve them determining no further review is necessary. All field studies must be assigned an AAC&UF number.

Research facility means any school, institution, organization, or person that uses or intends to use live animals in *research, tests, or experiments*, and that (1) purchases or transports live animals in commerce, or (2) receives funds under a grant, award, loan, or contract from a department, agency, or instrumentality of the United States for the purpose of carrying out research, tests, or experiments. (AWR, 9 C.F.R. §1.1)