

<i>NATIONAL MARINE FISHERIES SERVICE POLICY 04-112</i> Effective on: October 2019	
To be reviewed on: October 2024	
Science and Technology	
NMFS Animal Care and Use Policy	
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<i>SUMMARY OF REVISIONS:</i>	
<ol style="list-style-type: none"> 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; and 3. Text revised in multiple sections to clarify content including definitions. 	

I. Introduction

The National Oceanic and Atmospheric Administration’s (NOAA) National Marine Fisheries Service (NMFS) conducts and supports research activities involving live marine mammals, seabirds, and sea turtles. In 2007, the NMFS Science Board established a Task Team to develop a policy and an implementation plan for NMFS Animal Care and Use Committees in accordance with the Animal Welfare Act (AWA) and its implementing regulations (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 researchers on live marine mammals and sea turtles constitute humane treatment of those animals. This current document is an update to the 2015 directive based on recommendations from the three regional Institutional Animal Use and Care Committee (IACUC) Chairs, Office of Science and Technology (F/ST), and the Office of Protected Resources (F/PR).

Animal Welfare Act (AWA) 7 U.S.C. §2131 et seq.

The AWA charges the Secretary of Agriculture with promulgating regulations and standards for the humane handling, care, treatment, and transportation of animals by dealers, research

facilities, and exhibitors. For research facilities, requirements include annual reporting and establishing an IACUC to review protocols and assure compliance with the AWA. The AWA states that *“Each Committee shall be appointed by the Chief Executive Officer of each such research facility and shall be composed of a minimum of three members. Members shall possess sufficient ability to assess animal care, treatment, and practices in experimental research as determined by the needs of the research facility and shall represent society’s concerns regarding the welfare of animal subjects used at such facility.”* These requirements apply to federal and non-federal research facilities.

AWA requirements focus on the care and use of laboratory or captive animals, but the same principles apply to vertebrate species used in field research. The AWA exempts “field studies,” defined as *“any study done on free-living wild animals in their natural habitat, which does not involve an invasive procedure, and which does not harm or materially alter the behavior of the animals under study,”* from full review and approval by the IACUC.

For NMFS IACUC purposes, *“Intrusive (invasive) research refers to 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.)”* (See Section VI Glossary accompanying Procedural Directive). This definition is applicable to research on wild sea turtles, marine mammals, and seabirds. However, NMFS IACUCs, especially veterinary professionals will make final determinations on the invasiveness of specific protocols. Further, NMFS researchers will provide a detailed justification for any deviations from approved protocols or for defining a protocol as non-invasive.

Although field studies are exempted from IACUC review, NMFS IACUCs are required to preliminarily review all proposed marine mammal, sea turtle, and seabird field studies to determine whether they are in fact exempt. The IACUC Chair, designated member or full committee can approve them determining no further review is necessary. All research activities submitted for IACUC reviews including field studies must be assigned an Assurance of Animal Care and Use Form (AAC&UF) number.

Animal stranding response, rescue, rehabilitation, and post-release monitoring, as well as enhancement activities (e.g., vaccination programs) are generally exempt from IACUC reviews but PIs, including those operating under the Marine Mammal and Health and Stranding Response permits must still consult their regional IACUCs to determine if the proposed procedure is exempt or not.

U.S. Government Principles (USGP) for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training

In 1985, these principles were developed by the Interagency Research Animal Committee chaired by National Institute of Health (NIH). Specifically, whenever U.S. Government agencies perform or sponsor testing, research, or training procedures, the responsible Institutional Official (IO) shall ensure adherence to these (I-IX) [principles](#). A copy of these principles is attached to the accompanying procedural directive as an appendix. Further guidance on these principles can be obtained from the [Guide for the Care and Use of Laboratory Animals](#) prepared by the Institute for Laboratory Animal Research, National Academy of Sciences. For research on live marine mammals, seabirds, and sea turtles, the IACUCs will review and evaluate ‘humaneness’ of actions on the basis of adherence to USGP I-IX and the Guide for the Care and Use of Laboratory Animals, defined as “*humane care means those actions taken to ensure that laboratory animals are treated according to high ethical and scientific standards. Implementation of a humane care program and creation of a laboratory environment in which humane care and respect for animals are valued and encouraged underlies the core requirements of the Guide and the system of self-regulation it supports.*”

Marine Mammal Protection Act (MMPA)

NMFS IACUC reviews are required for all animal capture, handling, and invasive research conducted on captive and wild marine mammals by NMFS personnel. There are no definitions of “humane” in the AWA and AWAR and consistent with the original 2010 IACUC policy and procedural directive, NMFS IACUCs will continue to use the MMPA definition of “humane” in the MMPA (at 16 U.S.C. §1362, and MMPA regs at 50 C.F.R. § 216.3) to evaluate humaneness of the research conducted on wild marine mammals under 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.*”. This definition will be utilized in conjunction with 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 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.*”

Additional taxa-specific guidelines and best practices are provided in listed in Attachment I NMFS Animal Care and Use Committee Standard 04-114-01.

II. Objective

The Agency will carry out the requirements of the AWA and its implementing regulations at 9 C.F.R. §1.1 *et seq.* (AWAR) and follow the USGP. This policy will apply to all NMFS research on captive and free-ranging live marine mammals, seabirds, and sea turtles conducted by NMFS scientists. The following researcher types will be eligible for NMFS IACUC reviews:

- Research conducted by a NMFS Principal Investigator (PI) and scientific research permit holder.
- NMFS Co-Investigators (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.

Three regional IACUCs have been established to review animal use in research and recovery programs implemented by the Centers, regional offices, F/ST, and F/PR. The three regional NMFS IACUCs are 1): *Northeast/Southeast Science Centers' IACUC*, 2) *Pacific Islands/Southwest Science Centers' IACUC*, and 3) *Northwest/Alaska Science Centers' IACUC*. Researchers are advised to consult with their regional IACUCs regarding application procedures for submitting applications and seeking IACUC approval since this is outside the scope of the directive.

The MMPA definition and established USGP, AWAR, and relevant guidelines published by professional societies will inform humaneness determinations by the IACUC regardless of taxa. Once the AAC&UF is approved, it is considered an “approved protocol” that allows NMFS scientists to conduct the studies as described. However, approval to conduct research on live marine mammals, sea turtles, and seabirds, is still subject to the issuance of a scientific research permit and further approval per institutional procedures.

The IACUC prepares a Letter of Assurance of compliance with the AWA, the USGP, and NMFS IACUC policy that is valid for a **period of five years** and forwards it to the PI and IOs. PI or CIs from F/ST, F/PR, or other NMFS headquarters or regional office will submit AAC&UF forms to the appropriate regional IACUC depending on the study area. While the permitting and IACUC review processes can occur concurrently, IACUC approvals are a pre-condition for the issuance of a NMFS scientific research permit. Therefore, timely communication and coordination between the IACUCs and the NMFS Office of Protected Resources is essential. Often, the validity period of the IACUC Letter of Assurance and scientific research permit/s may not be aligned, and researchers are encouraged to contact their regional IACUCs to ensure that renewals or new

applications are submitted punctually, and similarly, researchers should contact the Office of Protected Resources for guidance on submitting complete applications to ensure expedient processing of the scientific research permit application. Seabird and (land-based) sea turtle researchers should follow United States Fish and Wildlife Service (USFWS) scientific research permitting processes and guidance as appropriate.

This approach fosters collaboration and consistency among the regional IACUCs. The Committees will follow the procedures outlined in the Procedural Directive 04-0114-01 entitled *NMFS Animal Care and Use Committee Standards*. This approach also provides Letters of Assurance that research protocols involving live marine mammals, seabirds, and sea turtles are being conducted in a humane fashion and assists F/PR in the issuance of MMPA and ESA marine mammal research permits to NMFS scientists.

III. Authorities and Responsibilities

This policy directive establishes the following authorities and responsibilities: In accordance with the AWAR in 9 C.F.R. §2.37, the Center Directors will be the IOs for NMFS IACUCs responsible for all research involving live marine mammals, seabirds, and sea turtles conducted or supported by the agency and assures compliance with AWA, AWAR, and USGP.

National direction and consistency will be established and maintained by F/ST in coordination and consultation with the Directors of the six Centers and associated IACUC Chairs, and relevant headquarters and regional offices.

The three regional NMFS IACUCs will review the AAC&UF or modifications to protocols. Each regional committee will represent more than one NMFS region and will have the same composition, additional duties, and responsibilities required of nonfederal research facilities under 9 C.F.R. §2.31, with two exceptions:

- The committee will report non-compliance with approved protocols or animal holding deficiencies to the IOs overseeing the research rather than to the U.S. Department of Agriculture Animal and Plant Health Inspection Service (APHIS);
- The IOs overseeing the research will be responsible for all research activity as approved by the regional NMFS IACUC and for the granting of all exceptions to approved protocols.

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, and

other established wildlife research animal use and care guidelines (e.g., ASM, USGP), and try to attend at least one Scientists Center for Animal Welfare (SCAW), which are IACUC training workshops 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 appropriate training as directed and available and by F/ST and the IACUC Chairs.

IV. Measuring Effectiveness

This Policy will be reviewed and updated if necessary in accordance with the [NMFS Policy Directive System](#).

V. References

This policy directive is supported by the references, appendix, and glossary listed in Attachment I. NMFS Animal Care and Use Committee Standard 04-114-01.

Signed  10/10/2019
Chris Oliver Date
Assistant Administrator for Fisheries