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<i>NATIONAL MARINE FISHERIES SERVICE INSTRUCTION 04-112-01</i>	
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<i>Science and Technology</i>	
<i>NMFS Animal Care and Use Policy - Procedural Directive</i>	
<i>NMFS ANIMAL CARE AND USE COMMITTEE STANDARDS</i>	
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Introduction

NOAA’s National Marine Fisheries Service (NMFS) conducts and supports activities that use live marine mammals and sea turtles. In 2007, the NMFS Science Board established a Task Team to develop policy and an implementation plan in accordance with the Animal Welfare Act (AWA) 7 U.S.C. §2131 et seq. and with the U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training (USGP) OSTP CFR May 20, 1985, Vol.50, No. 97.

The purpose of this procedural document is to establish nationally consistent standards for NMFS regional animal care and use committees. This approach fosters collaboration and consistency among regional NMFS Institutional Animal Care and Use Committees (IACUCs).

NMFS Animal Care and Use Committee Approach and Standards

1. Approach

Regional NMFS IACUCs: Includes three regional NMFS IACUCs with representation from each of the six NMFS Science Centers.

- **The pilot program in 2009/2010** will consist of the following regional NMFS IACUCs:
 - Northeast/Southeast Science Centers
 - Southwest/Pacific Islands Science Centers
 - Northwest/Alaska Science Centers
- NMFS researchers stationed in the Office of Protected Resources (OPR) or the Office of Science and Technology (S&T) will report to the regional IACUC in which their research is conducted, and fall under the review authority of that IACUC.
- The use of a non-NMFS IACUC (e.g., university IACUC) to review and approve NMFS research projects (i.e., when the principal investigator of the project is a NMFS employee) is not allowed.
- The NMFS IACUC Science Center Director or Office Director will submit an annual report USDA APHIS in compliance with AWR, 9 C.F.R. § 2.31 for Federal research facilities.
- On December 1st of each year, the Science Center Directors will report regional NMFS IACUC activities to the Assistant Administrator for Fisheries through the Director of Office of Science and Technology.
- By December 31st of each year, the Policy and Procedural Directives will be reviewed, revised, and renewed by the Office of Science and Technology.

2. Applicable Research for Review

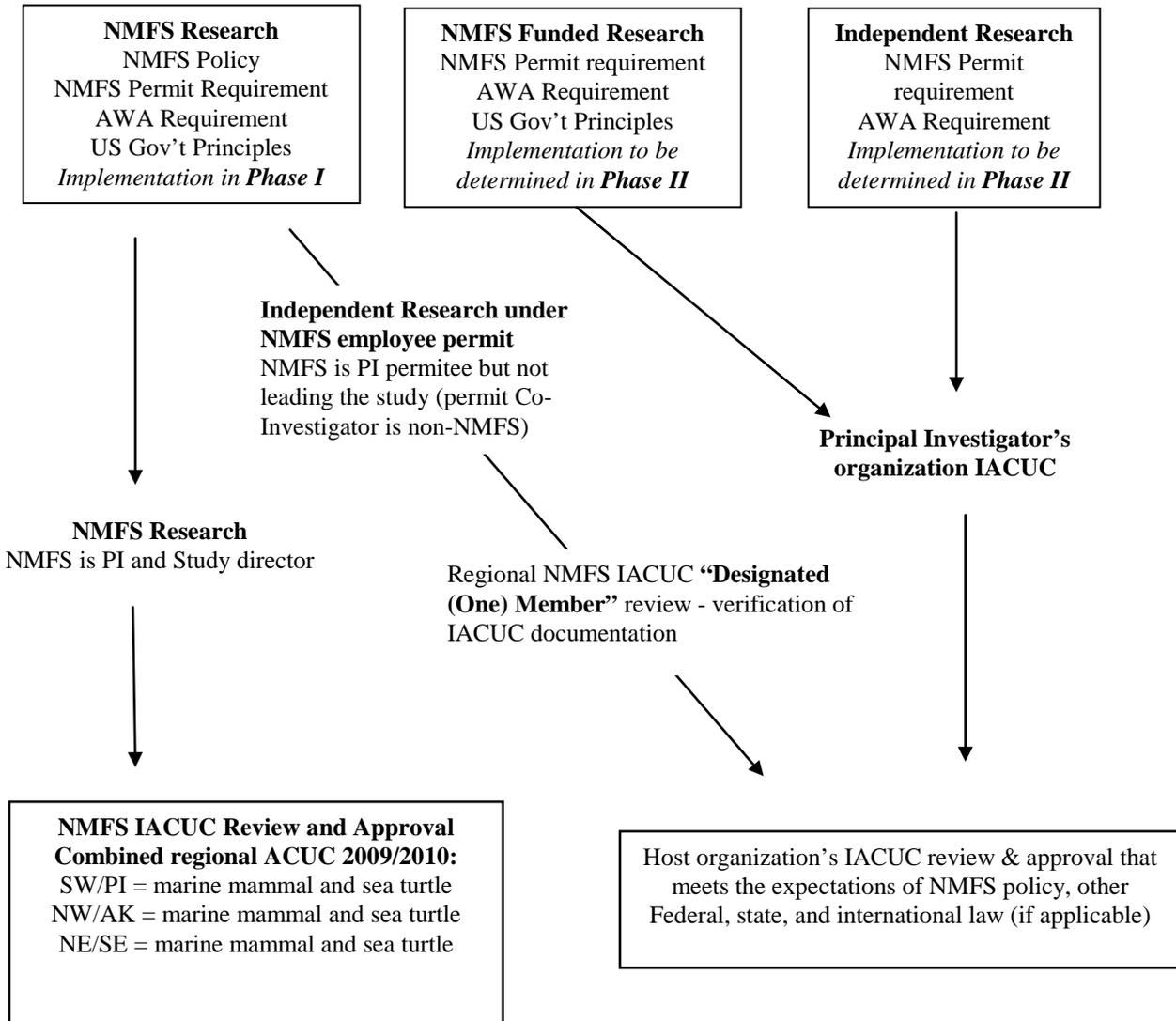
The following are types of research protocols that will be reviewed by NMFS IACUCs and the prescribed action:

- **Research conducted by a NMFS Principal Investigator (PI).**
 - The Regional NMFS IACUC will review research by NMFS PIs that are affiliated with or conduct research under the auspices of the relevant Science Center
 - The Regional NMFS IACUC will approve and through the IACUC Chair will communicate final decisions to the respective Science Center Director or the Director of OPR or S&T, as appropriate.
- Research conducted by a non-NMFS Co-Investigator under a NMFS Principal Investigator (i.e., Independent Research). All Co-Investigators (CI) working directly

under a NMFS employee's permit (i.e., NMFS is the principal investigator on the permit or permit holder) and conducting authorized independent research will submit the following documents to the Chair of the NMFS Regional IACUC for review prior to authorization of their research protocol:

- CI's proposed animal use protocols, OR
- CI's organization or institutional animal care and use documentation:
 - CI's organization IACUC policy approval (e.g., proof of adherence to AWA, an assurance statement filed with the Public Health Service, etc.)
 - Animal care and use protocol that is approved and signed by the CI's IACUC Chair including the duration of IACUC approval and IACUC Number
 - Any comments from the CI's IACUC regarding the protocol
- If provided with documentation from the CI's IACUC, the regional NMFS IACUC Chair may assign a voting IACUC to review and verify the documentation and recommend action (e.g., approve, approve pending modification, full committee review, or deny). See Figure 1.
- **Other Research.** Implementation to be determined in **Phase II** of this Procedural Directive
 - **NMFS Funded Research.** All NMFS supported and funded research will require an IACUC approval that meets the requirements of the AWA, other state and Federal laws, international laws (if applicable), and NMFS policy. This will require proof of IACUC approval and duration (i.e., approved research protocol and assurance statement) from the organization's IACUC Chair to be submitted with funding requests (and permit applications). See Figure 1.
 - **Non-NMFS funded research.** All other research will require an IACUC approval that meets AWA requirements, other state and Federal laws, international laws (if applicable), and NMFS policy. This will require documentation as prescribed by the NMFS permit office. See Figure 1.

Figure 1. Protocol Review and Approval Process



3. Standard IACUC Requirements in accordance with AWR 9 C.F.R. § 2.31

- **Appointment.** The Regional Science Center Directors will appoint and assemble their respective regional IACUC Committees. These committees will assess the NMFS Science Centers or Office research animal programs, facilities, and procedures. At this time, all members must be Federal employees.
- **Committee Composition.** The NMFS IACUC (with voting authority) will be composed of at least four 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 Science Center.
 - **IACUC Chair** is responsible for all administrative activities of the IACUC and

reports to the Science Center Director(s). The Chair is appointed by the Science Center Director(s) and is responsible for overseeing the coordination and implementation of the IACUC in compliance with this policy and AWR and selecting the members of the IACUC. This position should be held by a person with sufficient stature (e.g., seniority or tenure) who has direct access to the Science Center Director(s); has excellent communication, administrative, and facilitation skills; and will be impartial and maintain integrity of the IACUC. The Chair will serve a three-year term with an option to extend for another three years (i.e., six years total) and at the discretion of the Science Center Director(s).

- **Veterinarian** has expert knowledge of IACUC procedures and practices and is responsible for assuring activities involving live animals under the purview of the Science Center(s) are humane and follow the best possible animal care and field practices. The veterinarian will work closely with researchers in developing protocols for research and animal care and handling. The veterinarian will serve a three-year term with an option to extend for another three years (i.e., six years total) and at the discretion of the Science Center Director(s).
- **Nonaffiliated member** is not affiliated in any way with the regional NMFS Science Center other than as a member of the NMFS IACUC, and shall not be a member of the immediate family of a person who is affiliated with the regional NMFS Science Center. The intent of this member is to represent the general public interests in the proper care and treatment of animals. The Nonaffiliated 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 Science Center Director(s).
- **Researcher(s)** is/are practicing scientists with experience involving research with animals, 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) and at the discretion of the Science Center Director(s).
- **Alternate** members should also be designated to fill in when other IACUC members cannot review and vote on specific research protocols due to absence or conflict of interest.
- **IACUC Coordinator (optional)** is a non-voting member 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, assigning protocols for review by the IACUC or designated reviewers, 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.

- **Business Rules of NMFS IACUC (AWR, 9 C.F.R. § 2.31)**
 - **Review:** For all research, the NMFS researcher will submit a request for review of the proposed activity by completing the NMFS Animal Care and Use Assurance Application Form submitted to the regional NMFS IACUC Chair. The Chair determines whether the protocol requires a full committee review.
 - **Annual review of the status of the protocol** – the regional NMFS IACUC requires the principal investigator to annually report on the status of their research protocols, verify that completed activities were conducted in accordance with the approved protocol, describe any proposed departures from the approved protocols, and provide information about activities projected for the upcoming year.
 - **Quorum** - If full IACUC review is requested for a proposed activity, approval of that activity may be granted only after review at a convened meeting (face-to-face or via the internet) of a quorum of the IACUC, and with approval vote of a majority of the quorum present. For purposes of this Policy Directive, a quorum represents two-thirds of the voting IACUC membership. Suspension of an activity requires review by the full IACUC.
 - **Conflict of Interest** - No member may participate in the IACUC review or approval of an activity in which that member has a conflicting interest (e.g., is personally involved in the activity), except to provide information requested by the IACUC, nor may a member who has a conflicting interest contribute to the constitution of a quorum.
 - **Ad hoc consultants** – The IACUC may invite consultant 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 members of the research or other community with specialized disciplines (statisticians, animal health technicians, occupational health experts, information resource specialists).
 - **Professional guidelines** – The IACUC is encouraged to use guidelines and ethics established by professional societies (e.g., American Society of Mammalogists, Society for Marine Mammalogy, etc.) to assist with protocol review and assessment.
- **Duties of the NMFS IACUC (AWR, 9 C.F.R. § 2.31) (Table 1 summarizes specific requirements under each duty)**
 - **Reviews all marine mammal and sea turtle research** to determine whether full IACUC review is needed. This includes activities, protocols, and standard operating procedures.
 - **Evaluates** the training and experience of the research personnel.
 - **Reviews** the institution's (NMFS Science Center) animal care and use program at

- least every six months.
- **Inspects** animal care facilities and satellite facilities every six months. Inspection of research activities in the field is not required but is strongly encouraged and may be conducted with ad hoc members and/or photo documentation during research activities.
 - Submits to the Science Center Director(s) a **report** of these evaluations and correction plans for deficiencies.
 - **Investigates** concerns raised by the public or by laboratory or research personnel.
 - Makes **recommendations** regarding facilities, programs, and training.
 - Reviews and **approves** (or requires modifications or withholds approval of) proposal components.
 - **Suspends** an activity or entire research project involving animals if it does not comply with the NMFS Animal Care and Use Policy.
 - **Ensures** that fellow IACUC members are trained to be effective members of the IACUC.

Table 1. Detailed duties of the Animal Care and Use Committee as required under the AWR, 9 C.F.R. § 2.31

<i>Duties</i>	<i>Requirements</i>
Inspection and post award monitoring	<ul style="list-style-type: none"> ○ Semi-annually inspect laboratory and satellite facilities. ○ For research activities in the field, study areas that contain free-living animals in their natural habitat do not require inspection. However, monitoring of research activity for protocol compliance could be done by ad hoc members and/or photo documentation during study times. ○ Continue to monitor activities for the duration of the project.
Meetings - protocol review and business meetings	<ul style="list-style-type: none"> ○ Protocol reviews can be done in person or by video, conference call, or webinar ○ IACUC members may call for a full committee review of any submitted proposal or protocol ○ Conduct business meetings at least semi-annually to review IAUCU program, inspection reports, PI reports.
IAUCU records management	<ul style="list-style-type: none"> ○ Must document IACUC meeting minutes ○ All IACUC reviews must include minority views ○ Document protocol and facility deficiencies and include any compliance and corrective actions ○ IACUC member CVs ○ All records must be maintained for a minimum of 3 years. ○ IACUC member training certification documentation

<p>Reporting to Officials</p>	<ul style="list-style-type: none"> ○ To Science Center Director – following the IACUC semiannual meeting or more often if needed ○ To NMFS HQ (AA for Fisheries) - annually ○ To U.S. Department of Agriculture – Animal and Plant Health Inspection Service - The NMFS IACUC Science Center Director or Office Director will submit a report to USDA APHIS in compliance with AWR, 9 C.F.R. §2.36 for Federal research facilities - annually
<p>Evaluation of research protocols – Required information (Interim NMFS Animal Care and Use Assurance Application Template)</p>	<ul style="list-style-type: none"> ○ Project rationale and purpose of the proposed use of animals. ○ Justification of the species and number of animals requested. ○ Whenever possible, the number of animals should be justified statistically. ○ Address whether the research project meets the definition of observational study (AWR “Field Work” definition). If so, then a full IACUC review may not be necessary as decided by the NMFS IACUC Chair. ○ Availability or appropriateness of the use of less-invasive procedures, other species, isolated organ preparation, cell or tissue culture, or computer simulation (i.e., following the concept of the Three R’s – reduction, replacement, refinement). ○ Adequacy of training and experience of personnel in the procedures used. ○ Appropriate sedation, analgesia, and anesthesia ○ Invasiveness, Pain, and Stress scale – adapted from AWR, 9 C.F.R. § 2.36 <ul style="list-style-type: none"> - B applies only to animals held captive (non research status) - 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) ○ Avoidance of unnecessary duplication of experiments. ○ Criteria and process for timely intervention, removal of animals from a study, or euthanasia if painful or stressful outcomes are anticipated. ○ Postoperative care and treatment. ○ Method of euthanasia and/or disposition of animal or carcass. ○ Safety of working environment for personnel.

References

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

2. Animal Welfare Act Implementing Regulations (AWR) – 9 C.F.R. §2.37. 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 §2.31 with the following exceptions:
 - a. The Committee shall report deficiencies to the head of the Federal agency conducting the research rather than to APHIS; and
 - b. The head of the Federal Agency conducting the research shall be responsible for all corrective action to be taken at the facility and for the granting of all exceptions to inspection protocol.

3. U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training (USGP) OSTP CFR May 20, 1985, Vol.50, No. 97. 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 actually perform or sponsor such procedures, the responsible Institutional Official shall ensure that these principles are adhered to:
 - I. The transportation, care, and use of animals should be in accordance with the Animal Welfare Act (7 USC §2131 et. seq.) and other applicable Federal laws, guidelines, and policies.
 - II. 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.
 - III. 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.
 - IV. 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.
 - V. 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 unanaesthetized animals paralyzed by chemical agents.
 - VI. 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.
 - VII. The living conditions of animals should be appropriate for their species and contribute to their health and comfort. Normally, 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. In any case, veterinary care shall be provided as indicated.
 - VIII. 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.

IX. Where exceptions are required in relation 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, 2010.

5. Institutional Animal Care and Use Committee Guidebook, publication by the Applied Research Ethics National Association and the NIH Office of Laboratory Animal Welfare, 2nd Edition, 2002.

Glossary

Activity for 2010 NMFS Policy Statement and implementation timeline means research, research training and biological testing using live animals.

- New Activity means research requiring a permit modification or amendment or new permit application.
- Existing Research means research currently permitted by NMFS.

Animal for 2010 NMFS Policy Statement means **marine mammals and sea turtles**. It is the intent of NMFS to comply with the Animal Welfare Act (i.e., primarily warm blooded animals) and adhere to the U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research and Training, OSTP CFR May 20, 1985, Vol.50, No. 97 (i.e., all vertebrates). At this time, this Policy Statement specifically addresses care and use of marine mammals and sea turtles. The policy may be expanded to include additional taxa in the future.

Federal Agency means an Executive agency as such term 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 the federal awards under the Animal Welfare Act. (AWR, 9 C.F.R. §1.1 Definitions)

Federal Research Facility means each department, agency or instrumentality of the United States which 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. (AWR 9 C.F.R §1.1 Definitions)

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. (AWR, 9 C.F.R. §1.1 Definitions)

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 Definitions and 50 C.F.R. §216.3 Definitions)

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 affect behavior). (50 C.F.R. §216.3 Definitions).

NMFS Researcher for 2010 NMFS Policy Statement means any NMFS employees who uses or proposes to use live animal subjects or use of any NMFS facilities or platforms for the purpose of carrying out research, testing, or experiments using animal subjects.

- Principal Investigator (PI) 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. (50 C.F.R. §216.3 Definitions).
- 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. (50 C.F.R. §216.3 Definitions).

NMFS Supported Researchers include entities that receive funds, salaries, or support under a NMFS grant, award, agreement, or contract.

Permits means any permit issued under these sections which identify the number and kind of animals which are authorized to be taken or imported; the location and manner (which must be determined by the Secretary to be **humane**) in which they may be taken, or from which 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 AWR definition of field study and exempted from full IACUC review) 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 (except aerial surveys over pinniped rookeries at altitudes of less than 1,000ft). (50 CFR §216.45 (a)(3)).
- For Sea Turtles: research activities that may qualify as Observational Research include photo-identification studies, behavioral observations, vessel and aerial population surveys (above 500 ft).

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 Definitions).

Supported by references

This policy directive is supported by the reference listed in Policy Directive 04-011

Signed
Eric C. Schwaab /s/
Assistant Administrator for Fisheries