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NMFS Animal Care and Use Policy - Procedural Directive

NMFS ANIMAL CARE AND USE COMMITTEE STANDARDS

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SUMMARY OF REVISIONS: Changes in IACUC reporting structure and training requirements.

Signed _____/s/ _____ August 5, 2015_____

Ned Cyr

Date

Director, Office of Science and Technology

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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 and sea turtles. In 2007, the NMFS Science Board established a Task Team to develop policy and an implementation plan for NMFS Institutional Animal Care and Use Committees (IACUCs) 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, Office of Science and Technology Policy (OSTP) C.F.R. May 20, 1985, Vol.50, No. 97; and the Marine Mammal Protection Act (MMPA) to assure that research methods used by NMFS and NMFS-funded researchers on live marine mammals and sea turtles constitute humane treatment of those animals. The purpose of this procedural document is to establish consistent standards for NMFS Institutional Animal Care and Use Committees (IACUCs).

NMFS Animal Care and Use Committee Approach and Standards

A. Approach

- The program will consist of the following regional NMFS IACUCs:
 - Northeast/Southeast science centers’ IACUC
 - Pacific Islands/Southwest science centers’ IACUC
 - Northwest/Alaska science centers’ IACUC

- NMFS researchers stationed in the regional offices, Office of Protected Resources (F/PR), Office of Science and Technology (F/ST), or headquarters (HQ) office will report to the appropriate regional IACUC (region where research is conducted) and would fall under that IACUC review authority. As part of the IACUC review requirements, researchers will submit 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 personnel conducting research in multiple regions or oceans will submit all protocols within an AAC&UF to their regional IACUC.

- When the Principal Investigator (PI) or Co-Investigator (CI) is a NMFS employee, a NMFS IACUC must review the project.

- The Science Center Director/s, will be the Institutional Official (IO) for NMFS IACUCs overseeing activities carried out by NMFS PIs within their center or region. The IO is responsible for administering the regional program for animal use and care and ensuring compliance with NMFS policies and procedures.

- On **November 1st** each year, NMFS 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: number of animals used (by species, activity, date and location) within the IACUC approved protocol, any deviations from approved protocol, and planned activities for the next year in accordance with AWAR 9 C.F. R. §2.36.

- Center Directors will submit an annual ***Facilities Report*** (includes both captive and non-captive marine mammal research) to the appropriate western or eastern region of the United States Department of Agriculture (USDA) Animal Plant and Health Inspection Service (APHIS) by **December 1st** in compliance with AWA Implementing Regulations (AWAR) in 9 C.F.R. § 2.31 for Federal research facilities. *Applies only to research conducted on marine mammals during the previous fiscal year.*
- Annually on **January 31st**, each regional 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 AAC&UF reviews completed for the year, b) submission status of the Annual Research Facility Report to APHIS, and c) results of facilities inspections conducted (if applicable).
- The IACUC approval of AAC&UF and the Letter of Assurance will be valid for a period of 5 years and will not be applicable retroactively.

B. Applicable Research for Review

The following research protocols and actions will be reviewed by NMFS IACUCs. Note: NMFS IACUCs currently review research conducted on marine mammals and sea turtles only.

I. Research conducted by a NMFS PI

- The Regional NMFS IACUC will review AAC&UF covering research activities by NMFS PIs affiliated with or conducting research under the auspices of the relevant science center, regional or headquarters office.
- The Regional NMFS IACUC has authority to approve AAC&UFs and through the IACUC Chair communicate final decisions to the respective PI and IO. IACUC- approved AAC&UF are referred to as “approved protocols”.

II. Research conducted by a NMFS CI

- If research is conducted under a permit not held by a NMFS scientist, then the NMFS IACUC will review and accept Letters of Assurance (with an Assurance Number), which state the availability of valid research permits and “approved protocols” used to conduct research.
- NMFS CIs associated with NMFS fisheries observer programs can be added or removed during the 5-year period, but must undergo the

recommended training and adhere to approved protocols.

III. NMFS-Funded Research

- All NMFS supported and funded research will require an IACUC approval that meets the requirements of the AWA and NMFS policy. This will require proof of IACUC review, approval, and duration in a Letter of Assurance from the organization's IACUC Chair to be submitted with funding requests and annual reports as required.

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

- **Appointment:** The NMFS regional Science Center Directors will appoint regional IACUC Chairs to implement NMFS IACUC Policy and Procedures.
- **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 science center/office. All committee members must be federal employees, whether from NMFS/NOAA, or another federal agency.
 - i. **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 Science Center Director(s).
 - ii. **IACUC Chair** is responsible for all administrative activities of the IACUC and reports to the appropriate IO. The Chair is appointed by the Science 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 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), at the discretion of the Science Center Director(s).

- iii. **Non-affiliated member** is not affiliated 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 affiliated with the regional NMFS science center. 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 Science Center Director(s).
 - iv. **Researcher Member** is a practicing scientist with experience in animal 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, 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 an 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 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 marine mammal and sea turtle research scientists, statisticians, animal health technicians, occupational health experts, and information resource specialists.
- **Professional guidelines:** The IACUC and NMFS researchers are encouraged to use guidelines established by professional societies (e.g., American Society of Mammalogists, Society for Marine Mammalogy, American Society of Ichthyologists and Herpetologists) and the Institutional Animal Care and Use Committee Guidebook to assist with review of AAC&UFs.
- **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. Each IACUC member should take the equivalent of an IACUC 101 course at least once during their tenure and take additional training as available and appropriate.

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

- Review and approve the AAC&UF (or require modification or withhold approval of proposal components), assuring 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 promptly to PI and IO.
- Evaluate the training and experience of the research personnel.
- Facilitate preparation of Center Annual Facilities Report.
- Identify any deficiencies in compliance with “approved protocols”, recommend corrective steps, and inform the IO 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>Recommended 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 are not a USDA regulated species; sea turtle 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 full committee in person or via phone, 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, and reports of IACUC approved research.

<p>IACUC records management</p>	<ul style="list-style-type: none"> ▪ Meeting minutes must be recorded. ▪ 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. ▪ IACUC member training certification documentation and all other records must be maintained for a minimum of 5 years.
<p>Reporting</p>	<ul style="list-style-type: none"> ▪ The Institutional Official will submit the Annual Research Facility Report to USDA-APHIS in compliance with AWAR 9 C.F.R. §2.36. Note that according to APHIS Regulations federal facilities are not required to be registered with APHIS but they must file the annual reports. IACUCs will prepare these reports. ▪ Each regional IACUC will submit a brief annual summary report of IACUC reviews conducted to the Director/s of the relevant science center with a copy to the Director, F/ST. (Deadline Jan 31 of each year)
<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 and sea turtles is conducted in a humane manner in accordance with the AWA and USGP. ▪ In addition to meeting AWA and USGP requirements, 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. ▪ IACUCs have the responsibility of carrying out the intent of the AWA, AWAR and the USGP for the Utilization and Care of Vertebrate Animals Used in Testing, Research and Training “to ensure that animals intended for use in research facilities, or for exhibition purposes (or for pets) are provided humane care and

	<p>treatment”</p> <ul style="list-style-type: none"> ▪ IACUC reviews will assess whether procedures in AAC&UFs: (1) constitute humane treatment of animals as defined in the MMPA (<i>Methods of taking, import, export or other activity involves the least possible degree of pain and suffering practicable to the animals involved and that procedures that cause more than momentary or slight pain or distress to animals will be performed with appropriate sedatives, analgesics or anesthesia and that activities involve the least possible degree of pain and suffering practicable to the animal involved</i>) per AWAR 9 C.F.R. §2.31(d) and 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. ▪ 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. ▪ IACUC reviews may offer refinements to research (e.g., use of less-invasive procedures), and replacement of invasive techniques (e.g., modeling).
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	<ul style="list-style-type: none">▪ To facilitate reviews, regional IACUCs will periodically develop and update a collection of standard operating procedures (SOPs) (e.g., detailed descriptions of research procedures contained in past IACUC “approved protocols”). 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&U forms 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 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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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.*) – 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 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.
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) C.F.R. 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 research procedures, the responsible IO 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 U.S.C. §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 non-anaesthetized 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. 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.
- VII. 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 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](#), 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, William L. Gannon, and the Animal Care and Use Committee of The American Society of Mammalogists 2011. [Guidelines of the American Society of Mammalogists for the use of wild mammals in research](#). Journal of Mammalogy, 92(1):235–253.

Glossary

Activity for 2015 NMFS Policy and Procedural Directive means research, tests or experiments, using live marine mammals and sea turtles.

Animal for 2015 NMFS Policy and Procedural Directive means live marine mammals and sea turtles. It is the intent of NMFS to comply with the AWA (i.e., primarily warm blooded animals) and adhere to the USGP. At this time, this Policy Statement specifically addresses care and use of marine mammals and sea turtles.

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 the federal awards under the Animal Welfare Act. (AWAR, 9 C.F.R. §1.1 Definitions)

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 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. (AWAR 9 CFR §1.1 Definitions)

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 Definitions and 50 C.F.R. §216.3 Definitions). Further, from the AWAR: *“Procedures involving animals will avoid or minimize discomfort, distress and pain to the animals”* 9 C.F.R. Part 2, subpart C, Section 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 affect behavior). (MMPA 50

C.F.R. §216.3 Definitions)

NMFS Researcher Under this NMFS Procedural Directive and Policy Statement means any NMFS employee who uses or proposes to use live marine mammal 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.

NMFS-funded Researcher under this NMFS Procedural Directive and Policy Statement means any researcher (including non-NMFS researchers) who applies for and is awarded NMFS funding for scientific research on live animals.

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 Definitions)

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 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. (MMPA 50 C.F.R. §216.3 Definitions)

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 (except aerial surveys over pinniped rookeries at altitudes of less than 1,000 ft). (MMPA 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 (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 Definition)