



MARINE MAMMAL COMMISSION

31 July 2020

Ms. Jolie Harrison, Chief
Permits and Conservation Division
Office of Protected Resources
National Marine Fisheries Service
1315 East-West Highway
Silver Spring, MD 20910-3225

Re: Permit Application No. 23188
(Daniel Costa, Ph.D.,
University of California Santa Cruz)

Dear Ms. Harrison:

The Marine Mammal Commission (the Commission), in consultation with its Committee of Scientific Advisors on Marine Mammals, has reviewed the above-referenced permit application with regard to the goals, policies, and requirements of the Marine Mammal Protection Act (the MMPA). Dr. Costa proposed to conduct research on northern elephant seals in California during a five-year period—permit 19108 authorized similar activities.

The purpose of the research is to continue a long-term study investigating (1) population growth and status, (2) reproductive strategies, (3) behavioral and physiological adaptations for diving and fasting, (4) general and sensory physiology and metabolism, (5) health and disease, and (6) bioacoustics associated with northern elephant seals. Researchers would harass, observe, photograph/videotape¹, capture, handle, restrain, transport/translocate, temporarily hold in captivity, sedate, measure/weigh, sample, mark/tag, conduct procedures on², acoustically record, and attach instruments to or implant instruments in³ northern elephant seals of either sex and any age class each year (see the take table for specifics). Dr. Costa requested up to five mortalities per year, which could be either unintentional or intentional⁴, as well as authorization to import, receive, possess, and/or export samples from elephant seals. He also could intentionally kill up to 10 moribund or orphaned pups per year. Researchers would use various measures to minimize impacts on northern elephant seals and other pinnipeds that might be harassed incidentally and also would be required to abide by the National Marine Fisheries Service's (NMFS) standard permit conditions.

¹ Including using unmanned aircraft systems.

² Including (1) conducting auditory evoked potential (AEP) measurements, ultrasound, and playback experiments, (2) using a metabolic helmet and/or metabolic cage, and (3) administering Evan's blue dye, tritiated water, and/or various infusates and collecting serial blood samples.

³ Including surgical implantation of life history transmitter (LHX) tags.

⁴ Via euthanasia for humaneness purposes.

Application review process

NMFS provided the Commission with version eight of Dr. Costa's permit application and requested that the Commission informally review and comment on it. The application consisted of eight categories of proposed research projects, with dozens of invasive procedures requested under each project. The Commission provided numerous comments and questions on the application, many of which concerned insufficient descriptions of the methodologies for the invasive procedures and the types and numbers of procedures that could be conducted on different age classes of seals. Based on these deficiencies, it was difficult to assess whether the proposed activities met the humaneness criteria under section 104 of the MMPA. For example, it was not clear whether seals included in a subset of animals that would receive a certain combination of instruments and for which certain procedures would be conducted then could be included in a different subset that would receive a different combination of instruments and for which other procedures would be conducted at another point in time.

The Commission also informed NMFS that it could not comment meaningfully on the proposed duties of the principal investigator (PI) and co-investigators (CIs) because (1) it was unclear which activities the PI and CIs would be authorized to conduct, (2) in some instances, it was unclear which curriculum vitae (CV), qualification form (QF), or biosketch should be used to evaluate the qualifications of the PI and CIs since multiple versions had been provided for certain personnel, and (3) the qualifications provided in the CVs, QFs, and biosketches for the PI and CIs did not appear to support the duties listed in the personnel table. For example, based on the personnel table, Dr. McDonald would be authorized to surgically implant LHX tags. This is alarming because Dr. McDonald did not specify in her QF that she has conducted such surgeries or received formal surgical training via either veterinary or medical school⁵.

The Commission expected that NMFS would send *all* of the Commission's initial comments and questions on the application, the personnel table, and qualifications to the researchers for them to be addressed. However, based on the subsequent version of the application provided to the Commission, it was evident that NMFS had asked the researchers to respond to some, but not all, of the Commission's comments and questions and had provided only portions of some comments to the applicant. In addition, some of the responses provided by the researchers did not fully address the original questions, and another response prompted a new concern. Regarding the personnel table and qualifications, it was not clear which of the Commission's comments had actually been given to the applicant to address, leaving the Commission's questions largely unresolved. The Commission sent a revised set of 24 comments and questions⁶ to NMFS to provide to the researchers, including those that (1) still needed a response because they either had not been or had been only partially provided to the applicant, (2) required a more detailed or extensive response from the applicant, or (3) in one instance, had been raised based on responses from the applicant and which then needed to be addressed. It is worth noting that the comments and questions in this revised set focused on missing information that the Commission considered critical to making a decision regarding permit issuance. The Commission also reiterated its concerns regarding the personnel table and qualifications.

⁵ Similarly, Dr. Ponganis did not specify in his QF any experience surgically implanting LHX tags. However, he is at least a medical doctor.

⁶ Highlighted based on the type of response that was needed.

Nearly a month after receiving the supplementary comments and questions, NMFS informed the Commission that it would not forward the revised list to the applicant. NMFS indicated that the Commission's original 129⁷ informal comments and questions placed too much of a burden on the applicant, so it had removed those deemed unnecessary for evaluating the application against the issuance criteria⁸. NMFS indicated that it believed that the revised application addressed the requirements in the application instructions sufficiently. The Commission disagrees.

As stated in previous Commission letters⁹, the Commission poses questions or seeks additional information when either (1) the applicant has not provided all of the information required under the relevant (i.e., 2016) application instructions or (2) the information provided is not sufficiently complete or clear to support the findings required under the MMPA and an agency's implementing regulations or to serve as the basis for recommending appropriate permit conditions for inclusion in furtherance of MMPA section 104(b)(2). The Commission's comments and questions seek to ensure that the research methodologies are adequate, clear, and consistent so that the Commission and the public are able to assess whether the humaneness and *bona fide* research criteria have been met. Moreover, applications such as this one that includes numerous invasive procedures will inevitably receive a higher level of scrutiny to ensure that the potential to adversely impact an animal is minimized. The Commission regrets that NMFS chose not to provide the applicant with its revised set of comments and questions. This would have allowed the applicant to provide or clarify the information necessary to support the required findings or to serve as the basis for recommending appropriate permit conditions for inclusion in furtherance of MMPA section 104(b)(2).

Activities to be authorized under the permit

Because NMFS did not provide the applicant with the Commission's remaining concerns, information is still lacking and numerous deficiencies still exist in the descriptions of methodologies for the various proposed research projects. These make it impossible to evaluate whether the humaneness criteria would be met under section 104 of the MMPA¹⁰. For example, with respect to projects that involve instrumentation, the application specified up to 15 different types of internal or external instruments¹¹ that could be attached to juvenile¹² and adult elephant seals for the various projects and stated that no more than 8 instruments would be attached to¹³ or implanted in an animal at one time, with the additional proviso that the instrumentation would not exceed 10% of

⁷ This number was provided by NMFS. However, it is unclear how this number was calculated, as the Commission has counted approximately 100 comments, many of which were the same comment in different sections throughout the application to assist the applicant in inserting the relevant information in the appropriate sections. The Commission appreciates that the researchers provided sufficient responses to the majority of the comments provided to them.

⁸ In this case, the Commission informally noted that much of the information required in NMFS's application instructions was deficient or lacking in the original application—the large number of comments provided reflects this.

⁹ e.g., its [16 June 2020 letter](#) for Wild Space Productions and its [10 December 2019 letter](#) for U.S. Geological Survey.

¹⁰ The Commission will not reiterate in this letter all of the remaining issues, since that information has already been provided to NMFS.

¹¹ Some instruments are deployed as paired devices, such as the LHX tags, but this is not specified in the instrument table.

¹² Defined as weaned pups and young individuals up to 3 years old.

¹³ The researchers specified that no more than three instruments would be attached to an animal at a given time for Dr. Costa's previous application for permit 19108. The 2019 amendment request under that permit (which included the PO₂ and EKG, EEG, or near-infrared spectroscopy (NIRS)) specified that no more than four instruments would be attached

the seal's cross-sectional area and 2% of the seal's body mass. However, the application indicated that some seals could receive up to five different types of instruments (ranging from one to three devices and/or up to 6 electrodes each)¹⁴ plus a buoyancy drag block (see section 2.2.1.4 in the application). The combinations of the different types of instruments and drag blocks that could be deployed on a given individual were not specified¹⁵. Thus, it is impossible to determine whether the number and combination of tags that could be used would be detrimental to a seal's fitness and survival, particularly that of a newly weaned pup. It also is unclear what part of the body represents the "cross-sectional area" and what the maximum number of instruments that could be attached to an animal that is already carrying a drag block would be. The application specified that the drag block had comprised approximately 7 percent of the cross-sectional area of a seal in the past. The application indicated that no seal would carry both the drag block and the active acoustic tag, but it remained silent on whether those animals carrying a drag block would be instrumented with the PO₂, stomach temperature, and/or EKG, EEG, or NIRS instruments, all of which incorporate thermistors attached to the back as well. Further, the application did not specify the maximum number of instruments that could be placed on the jaw or head of an animal or its flippers, the combination of which could have severe implications for an animal's ability to forage and swim.

Furthermore, the application stated that as part of the proposed reproductive energetics study, up to 30 unweaned pups could be instrumented, yet there was no mention of (1) which instruments could be attached to a pup, (2) where on the animal they would be attached, (3) how many could be attached at one time, and (4) whether these metrics would differ based on the age or size of a pup (see section 2.2.1.7 in the application). Muscle and blubber biopsies also could be taken from pups during those activities, yet the minimum age of pups allowed to be sampled was not specified. It is not clear throughout the entire application whether procedures requested under other research projects, such as tagging, marking, and drone surveying (see section 2.2.1.1 in the application) and on-land sensory systems experiments (see section 2.2.1.8.b in the application), could be conducted on unweaned pups. For example, the application stated that only juvenile and adult seals would be dye-marked and flipper-tagged. However, in the description of basic handling procedures in the personnel table in Appendix 2, it stated that researchers could apply dye marks and insert flipper tags to seals of all ages. In addition, the applicant responded to one of the Commission's informal comments by specifying that personality and conspecific acoustic playback experiments would not be conducted on unweaned pups, yet the application stated that the experiments could be conducted on "females with pups" at the periphery of a group of seals. It is critical that the application clearly and consistently specify the procedures that would be conducted on different age classes of animals and what measures would be implemented to minimize impacts on very young animals.

to an animal at a given time. Therefore, under both permit 19108 and its 2019 amendment, half or less than half as many instruments were authorized to be attached to a seal at a given time compared with the eight instruments proposed in the current application, even though it doesn't appear that additional types of tags were included in the current application.

¹⁴ Which could exceed eight if all were deployed at the same time on a single seal.

¹⁵ NMFS did not provide this comment to the applicant. However, NMFS provided a similar comment regarding the number, combination/type, and placement of the various instruments and electrodes for the 2019 amendment request to the applicant, which was addressed by the researchers.

Based on the unanswered questions and remaining deficiencies in Dr. Costa's application, which could have been avoided entirely or in part if NMFS had provided all of the Commission's informal comments and questions to the applicant, the Commission, and presumably NMFS, cannot assess whether the activities proposed in Dr. Costa's application meet the humaneness criteria under section 104 of the MMPA.

Personnel qualifications

As mentioned previously, the Commission initially informed NMFS that it could not comment meaningfully on the personnel table and qualifications, and most of the issues raised remain in the final version of the application. For example, while the roles of the PI and CIs have been revised in the personnel table, it is still quite difficult to determine which procedure(s) the PI and each CI would be authorized to conduct under the permit. The column headers of the table are incongruent and include general categories such as "basic handling," specific activities such as "active acoustics," and age classes such as "juvenile." As stated in its [14 November 2019 letter](#) on NMFS's permit application instructions, the Commission recommends that the personnel table list the PI, CIs, and procedures and mark with an X each procedure to be conducted by each individual (see Table 1 in the Addendum as an example). Such tables¹⁶ have been used routinely by the majority of other applicants that have proposed to conduct live-capture procedures on pinnipeds¹⁷ and cetaceans¹⁸ and by other applicants that have proposed to conduct numerous invasive procedures¹⁹ in the last four years and can be easily populated based on the information provided in the QFs. Furthermore, not all procedures that could be conducted under the permit were included in the definitions of the column headers. For example, AEPs and urine sampling are missing from Appendix 2, and so it is not clear under which column header they would be conducted and thus which personnel would be authorized to conduct them. To provide clarity and reduce any ambiguity regarding the procedures that the PI and each CI are requesting authorization to conduct and ultimately would be authorized to conduct if the permit is issued, the Commission recommends that NMFS require Dr. Costa to provide a personnel table based on the example provided in the Addendum. Additionally, the Commission recommends that NMFS ensure that such a personnel table includes every procedure that could be conducted under the permit.

In addition, the Commission informally noted that more than one CV, QF, or biosketch was provided for the PI and multiple CIs, and it was unclear which one should be considered. This issue has not been resolved, and it remains unclear which should be used to assess those individuals' experience conducting the relevant procedures. Only one CV, QF, or biosketch should be provided for each researcher to be authorized under the permit.

Finally, many of the CVs, QFs, and biosketches that NMFS provided to the Commission for review lack sufficient detail regarding the experience of the PI or CI for some or all of the procedures he or she would be authorized to conduct²⁰. As the Commission has asserted in previous

¹⁶ Which include dozens of procedures and is modeled after the table included in Wells permit 20455.

¹⁷ e.g., Marine Mammal Laboratory (MML) permit 22289, MML permit 22678, Alaska Department of Fish and Game permit 20443.

¹⁸ e.g., Wells permit 20455.

¹⁹ e.g., Scripps Institution of Oceanography permit 22835 and Baird permit 20605.

²⁰ For example, several CIs would be authorized to conduct activities on seals using a metabolic helmet and/or metabolic cage, yet they did not describe in their QFs any prior experience conducting such activities. Furthermore, it is

letters²¹, details for every procedure that a PI or CI is being authorized to conduct must be provided explicitly in the CV, QF, or biosketch to ensure that the researcher has qualifications commensurate with the duties to be performed under the permit—this is consistent with NMFS’s implementing regulations (50 C.F.R. § 216.35(g)) and its 2016 application instructions. Moreover, if the PI or CI has only assisted others or received training to conduct an invasive procedure, resulting in a score of 1 for his or her level of experience with that procedure, he or she should not be authorized to conduct it unsupervised²². Only those individuals who have at least conducted an invasive procedure under supervision (Level 2 or greater) should be authorized to conduct such a procedure under the permit.

This concern is most pronounced with regard to personnel authorized to undertake invasive procedures. Despite the fact that the Commission raised its concern that Dr. McDonald would be authorized to surgically implant LHX tags without previous experience doing so and without receiving any formal surgical training in either veterinary or medical school, NMFS disagreed and contended that she had extensive experience with this procedure. NMFS specified that this experience was evident in her QF. As such, it does not appear that the agency provided the Commission’s comment to the researchers, and Dr. McDonald remains listed to conduct such a procedure under the permit (see the personnel table)²³. LHX surgeries should be conducted only by veterinarians or medical doctors, and preferably only by those with prior experience conducting the procedure. Having an untrained researcher with little or no relevant experience perform surgery could easily lead to complications and even to death of the seal.

While euthanasia is a procedure listed in the personnel table, neither the PI nor any of the CIs is designated to conduct it in the event of an emergency. Furthermore, it is unclear which activities Dr. Casper, DVM, would be authorized to conduct, as he was added to the revised personnel table but was not listed to conduct any of the procedures in it. If NMFS issues a permit to Dr. Costa, the Commission recommends that NMFS (1) require that the PI and each CI provide only one CV, QF, or biosketch that demonstrates his or her abilities to conduct the activities that he or she would be authorized to conduct under the permit, (2) authorize the PI and CIs to conduct only those invasive procedures that they have at least performed under supervision (Level 2 or greater), (3) authorize only veterinarians and medical doctors to surgically implant LHX tags and refrain from authorizing Dr. McDonald to do so, (4) ensure that the appropriate personnel are designated to conduct euthanasia, and (5) ensure that the personnel table indicates the procedures that Dr. Casper would be authorized to conduct.

not clear why “metabolic hood/chamber” was listed in Appendix 2 as an activity associated with transport, since it is described in the application under the fasting metabolism and diving development study.

²¹ e.g., MML permit 22289.

²² Level 1 experience denotes having assisted or received education/training in performing the procedure, but **not having successfully performed** the procedure. Level 2 experience denotes having performed the procedure while **under the supervision of or training** by an expert (e.g., PI, CI, or veterinarian). Level 3 experience denotes having performed the procedure **without supervision** by a PI or CI. Level 4 experience denotes being considered an **expert** in performing the procedure, and having **supervised or trained** others in conducting it.

²³ It also is unclear whether it was intended that Dr. McDonald be authorized to surgically implant LHX tags, as the application indicated that LHX implant procedures would be performed with a minimum of three people: a veterinarian, an anesthetist, and a non-sterile surgical assistant. This issue is further complicated because the surgery category in the personnel table includes placement of internal tags (both LHX and physiological instrumentation) and gas anesthesia—Dr. McDonald has experience with two of the three procedures. Fortunately, this issue could be easily resolved by the applicant implementing a table similar to Table 1 in the Addendum.

Ms. Jolie Harrison

31 July 2020

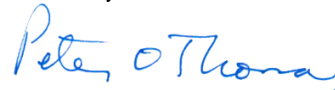
Page 7

Institutional Animal Care and Use Committee (IACUC) protocols

During its informal review of Dr. Costa's application, the Commission noted that some of the procedures requested were either missing entirely from the IACUC protocols, or details about the procedures were inconsistent between the application and protocols. For example, LHX tags, AEPs, and metabolic helmets and cages do not appear to be mentioned in the IACUC protocols and the source levels for acoustic tags in the protocols were lower than those specified in the application. The Commission asked NMFS whether other IACUC protocols contained the missing procedures or information but were not provided to the Commission, or alternatively, whether such protocols were being developed and, if so, when they were expected to be approved. The Commission also inquired whether new protocols would be submitted when one of the University of California Santa Cruz's protocols expires in October 2020. NMFS did not provide any of the Commission's comments about the IACUC protocols to the applicant and none of these issues have been addressed. If NMFS issues a permit to Dr. Costa, the Commission recommends that NMFS advise Dr. Costa that, prior to conducting any procedures, *all* research protocols reviewed and approved by the relevant IACUCs must match those activities authorized under the permit.

Please contact me if you have any questions regarding the Commission's recommendations.

Sincerely,



Peter O. Thomas, Ph.D.,
Executive Director

cc: Dr. Barbara Kohn, Animal and Plant Health Inspection Service

Addendum

Table 1. Example personnel table.

Activity	PI	CIs																				
	John Doe	Jane Doe	Jack Doe	Mary Doe	Kim Doe	Jill Doe	Sam Doe	Rob Doe	Ben Doe	Deb Doe	Jim Doe	Sarah Doe	Fred Doe	Tara Doe	Dave Doe	Harry Doe	Meer Doe	Kara Doe	Scott Doe	Karen	Erin Doe	
Photogrammetry/Remote video, Observation, behavior	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	
Collect scat	X	X	X		X	X	X	X						X	X		X	X	X			
UAS, VTOL and photogrametry	X						X	X			X		X	X					X	X	X	
Passive acoustic recordings	X	X	X	X	X			X		X	X				X		X					
Active acoustic playback experiments	X							X		X	X											
Handle	Administer drug, IV or IM and Anesthesia, gas with intubation-Juveniles	X	X		X	X	X	X		X	X		X		X	X	X	X		X		
	Administer drug, IV or IM-Females	X	X		X		X		X	X			X				X	X				
	Administer drug, IV or IM-Males	X			X			X		X								X				
	Ultrasound	X	X	X		X	X	X	X	X				X	X		X	X	X			
	AEP Testing	X	X	X															X			
	Metabolic helmet/cage	X											X									
	Sample, vibrissae, hair, milk	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	Sample, blood	X	X	X	X	X	X	X	X	X	X	X	X				X	X				X
	Administer Evan’s blue, stable isotopes, or hormones with serial blood sampling	X	X								X							X	X			
	Sample, skin or blubber biopsy	X	X			X	X	X		X								X	X			
	Sample, muscle biopsy	X	X			X	X			X								X	X			
	Sample, stomach lavage	X	X								X								X			
	Sample, urine	X	X								X								X			
	Sample, fecal enema	X	X								X								X			
	Instrument, external	X	X	X		X	X	X	X						X	X		X	X	X		X
	Instrument, internal (physiological instruments including thermistors and electrodes)		X								X								X			
	Instrument, internal (LHX tags)																		X			
	Transport/translocate and maintain in temporary captivity	X	X								X							X				
	Disentanglement	X	X	X		X	X	X	X		X				X	X		X	X	X		
Euthanasia	X			X				X		X								X				