

SUPPORTING STATEMENT
U.S. Department of Commerce
National Oceanic & Atmospheric Administration
Protocol for Access to Tissue Specimen Samples from the National Marine Mammal Tissue Bank
OMB Control No. 0648-0468

Abstract

This request is for extension of a current information collection. In 1989, the National Marine Mammal Tissue Bank (NMMTB) was established by the National Marine Fisheries Service (NMFS) Office of Protected Resources (OPR) in collaboration with the National Institute of Standards and Technology (NIST), Minerals Management Service (MMS), and the US Geological Survey/Biological Resources Division (USGS/BRD). The NMMTB provides protocols, techniques, and physical facilities for the long-term storage of tissues from marine mammals. Scientists can request tissues from this repository for retrospective analyses to determine environmental trends of contaminants and other substances of interest. The NMMTB collects, processes, and stores tissues from specific indicator species (e.g., Atlantic bottlenose dolphins, Atlantic white sided dolphins, pilot whales, harbor porpoises), animals from mass strandings, animals that have been obtained incidental to commercial fisheries, animals taken for subsistence purposes, biopsies, and animals from unusual mortality events through two projects, the Marine Mammal Health and Stranding Response Program (MMHSRP) and the Alaska Marine Mammal Tissue Archival Project (AMMTAP).

The purposes of this collection of information are: 1) to enable NOAA to allow the scientific community the opportunity to request tissue specimen samples from the NMMTB and, 2) to enable the Marine Mammal Health and Stranding Response Program (MMHSRP) of NOAA to assemble information on all specimens submitted to the National Institute of Standards and Technology's Biorepository (NIST Biorepository), which includes the NMMTB.

Under 16 U.S.C. 1421f section 407(d)(1) of the Marine Mammal Protection Act, the NMFS must establish criteria for access to marine mammal tissues in the NMMTB and make those available for public comment and review. This was accomplished through the proposed rule RIN 0648-AQ51, published on 11/12/2002, and codified in 50 CFR 216.47.

Justification

1. Explain the circumstances that make the collection of information necessary. Identify any legal or administrative requirements that necessitate the collection. Attach a copy of the appropriate section of each statute and regulation mandating or authorizing the collection of information.

This request is for extension of an approved information collection.

The purposes of this collection of information are: 1) to enable the National Oceanic and Atmospheric Administration (NOAA) to allow the scientific community the opportunity to request tissue specimen samples from the National Marine Mammal Tissue Bank (NMMTB) and 2) to enable the Marine Mammal Health and Stranding Response Program (MMHSRP) of NOAA to assemble information on all specimens submitted to the National Institute of Standards and Technology's Marine Environmental Specimen Bank (NIST Biorepository), which includes the NMMTB.

Analysis of biological samples and dissemination of research findings fulfills four of the primary goals of the MMHSRP. The MMHSRP was established in the late 1980s in response to growing concern about marine mammals washing ashore in United States (U.S.) waters. The MMHSRP goals are: 1) to facilitate collection and dissemination of data, 2) to assess health trends in marine mammals, 3) to correlate marine mammal health with available data on physical, chemical, environmental, and biological parameters, and 4) to coordinate effective responses to unusual mortality events.

The MMHSRP was formalized by the 1992 Amendments to the Marine Mammal Protection Act, and the National Marine Fisheries Service (NMFS) was designated as the lead agency to coordinate related activities. The program has the following components: 1) stranding networks, 2) responses/investigations of mortality events, 3) biomonitoring, 4) tissue/serum banking and 5) analytical quality assurance.

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There is only a very limited amount of samples available and the NMMTB emphasizes that the intended use of these tissue specimens be for retrospective analysis. Priority will be given to requests that fulfill the goals of the NMMTB, MMHSRP and to research that could otherwise not be accomplished.

2. Indicate how, by whom, and for what purpose the information is to be used. Except for a new collection, indicate the actual use the agency has made of the information received from the current collection.

A. INFORMATION ON REQUESTING SAMPLES FROM THE NIST BIOREPOSITORY

Requestors can apply as many times as they wish, but NMFS expects to receive only 5 applications per year.

1. Requestors must submit a written request, using the form included in this request and attaching a study plan to the MMHSRP Coordinator, NMFS/Office of Protected Resources.

2. The following specific information must be included in the request:

- a. A clear and concise statement of the proposed use of the banked tissue specimen. The applicant must demonstrate that the proposed use is consistent with the goals of the MMHSRP and the NMMTB.
- b. A copy of the applicant's scientific research permit. The applicant must demonstrate that the proposed use of the banked tissue is authorized by the permit. (if applicable)
- c. Name of principal investigator, official title, and affiliated research or academic organization.

- d. Specific tissue sample and quantity desired.
- e. Justification for use of the banked tissue.
- f. Research facility where analyses will be conducted must follow the Analytical Quality Assurance program which was designed to ensure the accuracy, precision, level of detection, and intercompatibility of data resulting from chemical analyses of marine mammal tissues. Standard reference materials for use in the analysis of marine mammal tissues can be purchased from the National Institute of Standards and Technology (NIST).
- g. Estimated date for completion of research, and schedule/date of subsequent reports.
- h. Agreement that all requests/findings will be reported to the NMMTB and the MMHSRP Program Manager.
- i. Agreement that credit and acknowledgment will be given to NMFS, U.S. Geologic Service, NIST, U.S Fish and Wildlife Service, the NMMTB, and the collector for use of banked tissues. The applicant shall insert the following acknowledgment in all publications, abstracts or presentations:

The specimens used in this study were provided by the National Marine Mammal Tissue Bank, which is maintained in the Marine Environmental Specimen Bank at NIST and which is operated under the direction of NMFS with the collaboration of United States Coast Guard (USCG), U.S. Fish and Wildlife Service (USFWS), and NIST through the Marine Mammal Health and Stranding Response Program [and the Alaska Marine Mammal Tissue Archival Project if the samples are from Alaska].

3. Upon submission, the NIST Environmental Specimen Bank Group Leader will send the request and attached study plan to the following entities which will function as the review committee:
 - a. Appropriate marine mammal management office for that particular species,
 - b. Representatives of the NMMTB Collaborating Agencies, and
 - c. Contributor, if applicable.

4. The applicant shall report to the MMHSRP Program Manager and the NIST Environmental Specimen Bank Group Leader all research findings based on use of the banked tissue in accordance with the schedule submitted with the application.

B. INFORMATION ON SUBMITTING SAMPLES TO THE NIST BIOREPOSITORY

The information on the NMMTB form will be collected whenever specimens are prepared for submission to the Bank. NMFS anticipates that approximately 20 organizations will submit specimen submission forms each year, with an annual total of 100 forms (as each of the 20 organizations is likely to submit multiple specimens).

The required form asks for basic information on the submitted sample such as gender, age, common and species name of the animal sampled. Indicator species include: harbor seal (*Phoca vitulina*), California sea lion (*Zalophus californianus*), northern fur seal (*Callorhinus ursinus*), ringed seal (*P. hispida*), pilot whale (*Globicephala melas*), harbor porpoise (*Phocoena phocoena*), Atlantic white-sided dolphin (*Lagenorhynchus acutus*), pygmy sperm whale (*Kogia breviceps*), bottlenose dolphin (*Tursiops truncatus*), rough-toothed dolphin (*Steno bredanensis*), common dolphin (*Delphinus delphis*), beluga whale (*Delphinapterus leucas*), bowhead whale (*Balaena mysticetus*), and polar bear (*Ursus maritimus*). Additional species have also been included. See Table 1 in the instructions for a list of all species collected as a part of the NMMTB. These data sheets should be shipped with all samples to the Bank.

The information is made available to the scientific community, aquariums, universities, government personnel, native Alaskans and any other partner organization of the MMHSRP. Sources of specimens include freshly-dead stranded animals, incidental takes in fishing activities, animals obtained through live capture and release programs, captive animals, animals taken by Alaskan natives for subsistence, and animals taken through aboriginal subsistence hunts according to treaty rights. The information is used to determine environmental trends of contaminants, establish baseline data on the health of marine animal populations, and correlate health with available data on physical, chemical, and environmental parameters and other analyses of interest.

It is anticipated that the information collected on the samples will be disseminated to the public or used to support publicly disseminated information. Although the information collected for sample requests is not expected to be disseminated directly to the public, results may be used in scientific, management, technical or general informational publications. As explained in the preceding paragraph, the information gathered has utility. NMFS will retain control over the information and safeguard it from improper access, modification, and destruction, consistent with NOAA standards for confidentiality, privacy, and electronic information. See response to Question 10 of this Supporting Statement for more information on confidentiality and privacy. The information collection is designed to yield data that meet all applicable information quality guidelines. Prior to dissemination, the information will be subjected to quality control measures and a pre-dissemination review pursuant to [Section 515 of Public Law 106-554](#).

Information Requirements and Needs and Uses of Information Collected

Item #	Requirement	Statute	Regulation	Form #	Needs and Uses
1	National Marine Mammal Tissue Bank Tissue Request Form	116 U.S.C. 1421f section 407(d)(1)	50 CFR 216.47	0468	Used by the public to request tissues from the NMMTB. Used by NMFS/NIST to track requests.
2	National Marine Mammal Tissue Bank Form	116 U.S.C. 1421f section 407(d)(1)	50 CFR 216.47	0468	Used by the public to submit samples to the NMMTB. Used by NMFS/NIST to track submissions.

3. Describe whether, and to what extent, the collection of information involves the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g. permitting electronic submission of responses, and the basis for the decision for adopting this means of collection. Also, describe any consideration of using information technology to reduce burden.

The specimen banking information sheets are available electronically (downloadable and fillable) through the MMHSRP website (<http://www.nmfs.noaa.gov/pr/health/tissue/>). Tissue bank request forms are available at http://www.nmfs.noaa.gov/pr/pdfs/health/tissue_request.pdf. Respondents do not need electronic access to fill out and submit the informational data sheets. They may also be obtained by calling the National Institute of Standards and Technology Hollings Marine Lab (843-460-9864).

4. Describe efforts to identify duplication. Show specifically why any similar information already available cannot be used or modified for use for the purposes described in Question 2

There is only one NIST Biorepository, the NIST Biorepository and only one NMMTB, so researchers and stranding network participants can only submit and/or request specimens to/from this bank

5. If the collection of information impacts small businesses or other small entities, describe any methods used to minimize burden.

This collection of information affects the scientific community. Part of the scientific community is composed of small businesses. However, the burden is not considered to be significant, since only about 5 applicants will be applying for a tissue specimen sample and the estimated time for each request is two hours; 20 respondents will submit approximately 5 samples annually, at 45 minutes each.

In order to minimize burden to small entities, the federal program pays for collection of specimens by small entities through contracts. Additionally, Prescott Grant recipients are paid for their sample collection work through the grant or subcontract. The Prescott Grant Program is conducted by the Secretary of Commerce to provide grants or cooperative agreements to eligible stranding network participants for 1) recovery and treatment (e.g., rehabilitation) of stranded marine mammals, 2) data collection from living or dead stranded marine mammals, and 3) facility upgrades, operation costs and staffing needs directly related to the recovery and treatment of stranded marine mammals and collection of data from living or dead stranded marine mammals. Shipping costs for tissue samples are borne by a collaborating agency, the National Institute of Standards and Technology (NIST). Copying costs should be minimal.

6. Describe the consequence to Federal program or policy activities if the collection is not conducted or is conducted less frequently, as well as any technical or legal obstacles to reducing burden.

If this information collection is not conducted, the specimens will be of minimal use to the scientific community or to the statutory requirements of the Marine Mammal Protection Act. The NIST Biorepository provides researchers specimens that have been collected in a systematic and well-documented manner for comparing results over time to identify whether environmental and health trends exist. Without background information on all specimens submitted to the Bank, scientists cannot conduct comparative and retrospective analyses or interpretation on archived marine mammal tissues.

7. Explain any special circumstances that would cause an information collection to be conducted in a manner inconsistent with OMB guidelines.

The collection will be conducted in a manner that is consistent with OMB guidelines.

8. If applicable, provide a copy and identify the date and page number of publications in the Federal Register of the agency's notice, required by 5 CFR 1320.8 (d), soliciting comments on the information collection prior to submission to OMB. Summarize public comments received in response to that notice and describe actions taken by the agency in response to these comments. Specifically address comments received on cost and hour burden.

On January 13, 2021, a notice of information collection, request for comment was published in the Federal Register (86 FR 2647) to solicit public comments on this data collection. No comments were received.

NMFS reached out to several previous applicants in an effort to obtain their views on the availability of data, frequency of collection, the clarity of instructions and recordkeeping, disclosure, or reporting format (if any), and on the data elements to be recorded, disclosed, or reported. No responses were received.

9. Explain any decision to provide any payment or gift to respondents, other than remuneration of contractors or grantees.

There is no provision to provide any payment or gift to participants in this request for tissue specimen samples.

10. Describe any assurance of confidentiality provided to respondents and the basis for the assurance in statute, regulation, or agency policy. If the collection requires a systems of records notice (SORN) or privacy impact assessment (PIA), those should be cited and described here.

NMFS does not store information about respondents by a unique identifier and as such, this collection does not require a System of Records.

11. Provide additional justification for any questions of a sensitive nature, such as sexual behavior or attitudes, religious beliefs, and other matters that are commonly considered private. This justification should include the reasons why the agency considers the questions necessary, the specific uses to be made of the information, the explanation to be given to persons from whom the information is requested, and any steps to be taken to obtain their consent.

There are no sensitive questions.

12. Provide estimates of the hour burden of the collection of information.

NMFS estimates that approximately 5 applicants will be requesting tissue specimen samples and reporting on their projects (two responses per respondent). The estimated time required to fill out the application is 1 hour. The estimated time to report research findings is 2 hours.

5 applicants x 2 response x (1+2) hours = 10 responses and 15 hours. The applicants will all be marine mammal researchers (Zoologists and Wildlife Biologists). The BLS's Occupational Outlook Handbook lists the average hourly wage of Zoologists and Wildlife Biologists as \$32.31.

Burden hours for submitting specimen samples: NMFS estimates that the total number of respondents is 30 people, with an average of 3 times per year. The annual average of submissions is 90. The estimated time to fill out the informational data sheet is 45 minutes. Submissions are split amongst researchers (approximately 25 responses) and subsistence harvest hunters (approximately 5 responses). The BLS's Occupational Outlook Handbook lists the average hourly wage of Zoologists and Wildlife Biologists as \$32.31. By definition, subsistence hunters are not paid for hunting.

Total for both information collections is 100 response, 83 hours, and \$2,310.17.

Information Collection	Type of Respondent (e.g., Occupational Title)	# of Respondents/year (a)	Annual # of Responses / Respondent (b)	Total # of Annual Responses (c) = (a) x (b)	Burden Hrs / Response (d)	Total Annual Burden Hrs (e) = (c) x (d)	Hourly Wage Rate (for Type of Respondent) (f)	Total Annual Wage Burden Costs (g) = (e) x (f)
National Marine Mammal Tissue Bank Tissue Request Form	Zoologists and Wildlife Biologists	5	2	10	3	30	\$32.31	\$969.30
National Marine Mammal Tissue Bank Form		30	3	90	0.75	67.50		\$1,825.51
National Marine Mammal Tissue Bank Form	Zoologists and Wildlife Biologists	25	3	75	0.75	56.25	\$32.31	\$1,825.51
National Marine Mammal Tissue Bank Form	Subsistence hunter	5	3	15	0.75	11.25	\$0	\$0
Totals				100		97.5		\$2,794.81

13. Provide an estimate for the total annual cost burden to respondents or record keepers resulting from the collection of information. (Do not include the cost of any hour burden already reflected on the burden worksheet).

There are no capital costs or operating and maintenance costs associated with this information collection.

National Marine Mammal Tissue Bank Tissue Request Form: The total annual cost to the applicant for requesting tissue specimen samples and reporting research findings would be in postage and copying; however submission of these request forms and research findings may be made electronically. We estimate that 1 of the 5 applicants will submit via postal mail:

Postage and copying: \$4.07 per applicant

Total cost: 1 x \$4.07 = \$4.07

National Marine Mammal Tissue Bank Form: Shipping and sample homogenization costs for tissue samples are borne by a collaborating agency, the National Institute of Standards and Technology (NIST) (all samples are homogenized before shipping). Thus, the only cost for tissue sample submission is for copying the Tissue Bank Submission Form enclosed with each sample:

Copying: 5 pages x \$0.16 = \$0.80 per tissue sample

90 submissions per year = 90 x \$0.80 = \$80.00 total annual cost burden.

Total costs for all information collection requirements: \$4.07 + \$72.00 = \$76.07

Information Collection	# of Respondents/year (a)	Annual # of Responses / Respondent (b)	Total # of Annual Responses (c) = (a) x (b)	Cost Burden / Respondent (h)	Total Annual Cost Burden (i) = (c) x (h)
National Marine Mammal Tissue Bank Tissue Request Form	1	1	1	\$4.07	\$4.07
National Marine Mammal Tissue Bank Form	30	3	90	\$0.80	\$72.00
TOTALS			91		\$76.07

14. Provide estimates of annualized cost to the Federal government. Also, provide a description of the method used to estimate cost, which should include quantification of hours, operational expenses (such as equipment, overhead, printing, and support staff), and any other expense that would not have been incurred without this collection of information.

Cost Descriptions	Grade/Step	Loaded	% of Effort	Fringe (if	Total Cost to
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		Salary /Cost		Applicable)	Government
NIST Oversight	ZP III/IV	\$60,000	10		\$6,000
Contractor Cost		\$0	\$0	\$0	\$0
Travel					\$0
Other Costs:					\$0
TOTAL					\$6,000

15. Explain the reasons for any program changes or adjustments reported in ROCIS.

Minor changes were made to the National Marine Mammal Tissue Bank Form. Most changes were grammatical. While no new data will be collected, two changes were made to existing data fields, to streamline data collection. Specifically, instead of relying on a “please specify” text field, more checkbox options have been added to the “collection type” field, and the “method used to age” field on the National Marine Mammal Tissue Bank Form. These checkboxes represent common answers submitted via the text field, and by adding more checkbox options, form users will not need to write out common answers to these questions. No changes have been made to the National Marine Mammal Tissue Bank Tissue Request Form.

Information Collection	Respondents		Responses		Burden Hours		Reason for change or adjustment
	Current Renewal / Revision	Previous Renewal / Revision	Current Renewal / Revision	Previous Renewal / Revision	Current Renewal / Revision	Previous Renewal / Revision	
National Marine Mammal Tissue Bank Request Form	5	5	10	10	30	15	Increase in burden hours due to previous administrative error in not accounting for 2 responses from each respondent Increase in respondents as the Tissue Bank is getting submissions from a larger number of people, though the overall amount of responses has decreased as many more are one-off submissions, with fewer regular submissions from the smaller group of researchers.
National Marine Mammal Tissue Bank Form	30	20	90	100	67.50	75	
Total for Collection	35	25	100	110	98	90	
Difference	10		-10		8		

Information Collection	Labor Costs		Miscellaneous Costs		Reason for change or adjustment
	Current	Previous	Current	Previous	
National Marine Mammal Tissue Bank Request Form	\$969.30	NA	4	4	
National Marine Mammal Tissue Bank Form	\$1,825.51	NA	72	80	
Total for Collection	\$2,795	NA	76	84	
Difference	\$2,795		-\$8		

16. For collections of information whose results will be published, outline plans for tabulation and publication. Address any complex analytical techniques that will be used. Provide the time schedule for the entire project, including beginning and ending dates of the collection of information, completion of report, publication dates, and other actions.

Results of analyses and studies assessing marine animal health and environmental trends utilizing the archived specimens from the Bank will be published by researchers and scientists. These results will be presented in scientific conferences and peer-reviewed journals and books.

The NIST will publish reports on trends in marine mammal health and environmental parameters. Collectors or submitters will be acknowledged or offered co-authorship in all public documents. NOAA has no plans at this time to make the results of the information collection available to the public over the Internet.

17. If seeking approval to not display the expiration date for OMB approval of the information collection, explain the reasons that display would be inappropriate.

The agency plans to display the expiration date for OMB approval of the information collection on all instruments.

18. Explain each exception to the certification statement identified in "Certification for Paperwork Reduction Act Submissions."

On behalf of this Federal agency, I certify that the collection of information encompassed by this request complies with [5 CFR 1320.9](#) and the related provisions of [5 CFR 1320.8\(b\)\(3\)](#).