

**SUPPORTING STATEMENT
PROTOCOL FOR ACCESS TO TISSUE SPECIMEN SAMPLES FROM THE
NATIONAL MARINE MAMMAL TISSUE BANK
OMB CONTROL NO. 0648-0468**

A. JUSTIFICATION

1. Explain the circumstances that make the collection of information necessary.

This request is for revision and extension of the information collection (there is now a tissue bank request form, where previously there was only a protocol with instructions).

The purposes of this collection of information are: 1) to enable 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 Biomonitoring Specimen Bank (Bank), 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 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.

The NMMTB was established in 1992 as a component of the National Biomonitoring Specimen Bank and 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 analyses of interest. The NMMTB collects, processes, and stores tissues from specific indicator species (e.g., Atlantic bottlenose dolphins, Atlantic white sided dolphins, pilot whales and harbor porpoise), 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.

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](#).

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. Explain how, by whom, how frequently, and for what purpose the information will be used. If the information collected will be disseminated to the public or used to support information that will be disseminated to the public, then explain how the collection complies with applicable NOAA Information Quality Guidelines.

A. INFORMATION ON REQUESTING SAMPLES FROM THE BANK

Requestors can apply as many times as they wish, but NMFS expects to receive only 20 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.
 - 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 (all research findings based on use of the banked tissue in accordance with the schedule submitted with the application).
 - 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 (Department of the Interior), 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 National Biomonitoring 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 MMHSRP Program Manager 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 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 BANK

The information on the NMMTB form will be collected whenever specimens are prepared for submission to the Bank. 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*), polar bear (*Ursus maritimus*). Additional species have also been included. See Table 1 in the instructions (examiner's guide) 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](#).

3. Describe whether, and to what extent, the collection of information involves the use of automated, electronic, mechanical, or other technological techniques or other forms of information technology.

The specimen banking information sheets will be 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 Science and Technology, Hollings Marine Lab (843-762-8952).

4. Describe efforts to identify duplication.

There is only one National Biomonitoring Specimen Bank and only one NMMTB, so researchers and stranding network participants can only submit and/or request specimens to/from this bank. Since many of the animals on which information will be submitted have been stranded and stranding report (“Level A”) forms have been completed under OMB Control No. 0648-0178, the two databases will retrieve duplicate information from the other forms.

5. If the collection of information involves small businesses or other small entities, describe the 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 20 applicants will be applying for a tissue specimen sample and the estimated time for each request or report is two hours.

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 (NIST). Copying costs should be minimal.

6. Describe the consequences to the Federal program or policy activities if the collection is not conducted or is conducted less frequently.

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 Bank 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. Scientists cannot conduct comparative and retrospective analyses or interpretation on archived marine mammal tissues without background information on all specimens submitted to the Bank.

7. Explain any special circumstances that require the collection to be conducted in a manner inconsistent with OMB guidelines.

The collection is consistent with OMB guidelines.

8. Provide information on the PRA Federal Register Notice that solicited public comments on the information collection prior to this submission. Summarize the public comments received in response to that notice and describe the actions taken by the agency in response to those comments. Describe the efforts to consult with persons outside the agency 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.

A Federal Register Notice, published on May 3, 2011 (76 FR 24862), solicited public comments. One comment was received requesting instructions on how to comment. We did not receive a comment after the explanation via e-mail.

The MMHSRP has consulted with scientists from the U.S. Geologic Service, NIST, and the USFWS regarding the availability of data to requesters. These collaborating agencies are also principal representatives of the NMMTB.

9. Explain any decisions to provide payments or gifts 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 assurance in statute, regulation, or agency policy.

No confidentiality is promised or provided.

11. Provide additional justification for any questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private.

There are no sensitive questions.

12. Provide an estimate in hours of the burden of the collection of information.

Burden hours for requesting tissue specimen samples: NMFS estimates that approximately 20 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 2 hours. The estimated time to report research findings is 2 hours.

$20 \text{ applicants} \times 2 \text{ hours} \times 2 \text{ times per year} = 40 \text{ responses and } 80 \text{ hours.}$

Burden hours for submitting specimen samples: NMFS estimates that the total number of respondents is 30 people, with an average of a little over 3 times per year. The annual average of submissions is 100. The estimated time to fill out the informational data sheet is 45 minutes.

$100 \text{ submissions} \times 45 \text{ minutes}/60 \text{ minutes} = 100 \text{ responses and } 75 \text{ hours.}$

Total for both information collections is 140 responses and 155 hours.

13. Provide an estimate of the total annual cost burden to the respondents or record-keepers resulting from the collection (excluding the value of the burden hours in Question 12 above).

The total annual cost to the applicant for requesting tissue specimen samples and reporting research findings is:

Postage and copying: \$4.08 per applicant
Total cost: $20 \times \$4.08 = \$82.$

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

Copying: $5 \text{ pages} \times \$0.16 = \$0.80 \text{ per tissue sample}$
 $100 \text{ submissions per year} = 100 \times \$0.80 = \$80 \text{ total annual cost burden.}$

Total costs for all information collection requirements: $\$82 + \$80 = \$162.$

14. Provide estimates of annualized cost to the Federal government.

There will be no annualized cost to the Federal government other than for regular staff time: 100 hours at \$35 per hour, totally \$3,500.

15. Explain the reasons for any program changes or adjustments.

Adjustment: Increased postage costs added \$10 to the total recordkeeping/reporting cost.

*All samples are homogenized before shipping.

16. For collections whose results will be published, outline the plans for tabulation and publication.

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 why display would be inappropriate.

Not Applicable.

18. Explain each exception to the certification statement.

There are no exceptions.

B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

This collection of information does not employ statistical methods.