1SUPPORTING STATEMENT A FOR

PAPERWORK REDUCTION ACT SUBMISSION

National Park Service Institutional Animal Care and Use Committee (NPS IACUC) Amendment, Annual Review, Field Study, Concurrence, and General Submission Forms

OMB Control Number 1024--0265

Terms of Clearance: None.

Justification

1. Explain the circumstances that make the collection of information necessary. Identify any legal or administrative requirements that necessitate the collection.

The National Park Service (NPS) is requesting a renewal of this collection. Pursuant to the Animal Welfare Act (AWA), Animal Welfare Act Regulations (AWAR), and the Interagency Research Animal Committee (IRAC), any entity or institution that uses vertebrate animals for research, teaching, or training purposes must have an oversight committee to evaluate all aspects of that institution's animal care and use. To be in compliance, the NPS is responsible for managing and maintaining an Institutional Animal Care and Use Committee (IACUC) that provides the experience and expertise necessary to assess and approve all research, teaching, and training activities involving vertebrate animals on NPS-managed lands and territories.

All research, teaching, and training projects involving the use and care of vertebrate animals taking place on NPS territories must be reviewed and approved by the NPS IACUC prior to starting.

As determined by the AWA, the NPS IACUC is a self-regulating entity that currently consists of a Chair, a veterinarian to serve as the "Attending Veterinarian," and another individual to serve as the "Unaffiliated Member At-Large."

Legal Authorities:

- ***Animal Welfare Act,*** 7 U.S.C. 2131-2159; ***§2.31, d, 1***
- ***54 USC 100701*** *Protection, interpretation, and research in System" (formally* ***The National Park Service Act of 1916)***
- ***54 USC 100702*** *National Park System Resource Inventory and Management*

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. Be specific. If this collection is a form or a questionnaire, every question needs to be justified.

The NPS IACUC will continue to use this information to ensure that sufficient and relevant information is available to evaluate proposed research projects, teaching, or training activities involving the use of animals within NPS units. Each animal project must be reviewed by the NPS IACUC committee annually. A review of a new General Submission or Concurrence form is required every three years, or less frequently for ongoing activities. The review process covers the following points:

- Identification of the species and approximate number of animals to be used.
- Rationale for involving animals, the appropriateness of the species, and numbers used.
- A complete description of the proposed use of the animals.
- A description of procedures designed to assure that pain and distress experienced by animals will be limited to that which is unavoidable in the conduct of scientifically valuable research, and that analgesic, anesthetic, and tranquilizing drugs, or other effective methods, will be used where indicated and appropriate to minimize distress and pain to animals.
- Description and support of any euthanasia method to be used.

In review, the IACUC is required to ensure that the proposed work is consistent with the treatment of animals as described in the AWA, and that the following points are covered:

- Procedures with animals will avoid or minimize discomfort, distress, and pain to the animals, consistent with sound research design.
- Procedures that may cause more than momentary or slight pain or distress to the animals will be performed with appropriate sedation, analgesia, or anesthesia unless the procedure is justified for scientific reasons in writing by the investigator.
- Animals that would otherwise experience severe or chronic pain or distress that cannot be relieved will be painlessly killed at the end of the procedure or, if appropriate, during the procedure.
- The living conditions of animals will be appropriate for their species and contribute to their health and comfort. The housing, feeding, and nonmedical care of the animals will 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.
- Medical care for animals will be available and provided as necessary by a qualified veterinarian.

- Personnel conducting procedures on the species being maintained or studied will be appropriately qualified and trained in those procedures.
- Methods of euthanasia used will be consistent with the recommendations of the American Veterinary Medical Association (AVMA) Panel on Euthanasia unless a deviation is justified for scientific reasons in writing by the investigator.

1. *The General Submission form:* This form has not been changed from the 2020 version. This form requires the following information:

- A project narrative that includes: the title, a statement of the objectives to be addressed, the scope of the proposed project, a literature review for alternatives to potentially painful or distressful procedures, and a description of the methods and procedures to be used.
- A description of the qualifications of the principal investigators, all personnel involved, and delegated attending veterinarians on the project.
- Details and descriptions of animals used in the project.
- A search for alternatives to procedures that may cause more than momentary or slight pain and distress to the animals
- Sections involving surgical procedures are hidden unless the researcher is planning to conduct surgical activities, thereby reducing the burden of completion by the researcher and of time for review by the IACUC members
- A list of the permits necessary to conduct the project.
- A signed declaration of compliance with the procedures and methods outlined in the AWA, its Regulations, and the IRAC.

2. *The Concurrence and Field Study forms:* These forms have not been changed from the 2020 version. These are used for projects that will not require the same level of review or information as the General Submission form and will reduce the time for completion by a total of 235 hours. These forms will require the following information:

- A project narrative that includes: the title, a statement of the objectives to be addressed, the scope of the proposed project, and description of the methods and procedures to be used.
- A description of the qualifications of the principal investigators, all personnel involved, and delegated attending veterinarians on the project.
- Details and descriptions of animals used in the project, if not provided in an approved protocol from an IACUC outside of NPS or in a form from another oversight agency.

- A signed declaration of compliance with the procedures and methods outlined in the AWA, its Regulations, and the IRAC.

3. *The Amendment and Annual Review forms**:*** These forms have not been changed from the 2020 version. Both forms will require the following information:

- Identifying any changes to the approved IACUC submissions including additions or deletions of personnel, species or numbers to be used, procedural changes, or refinements.
- A signed declaration of compliance with the procedures and methods outlined in the AWA, its Regulations, and the IRAC.

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 and specifically how this collection meets GPEA requirements

Submissions will be 100% electronic. There are no changes to the content of the currently approved forms. Information related to the forms is on the program's website: https://www.nps.gov/orgs/1103/iacuc.htm.

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 Item 2 above.**

There is no duplication of effort. The NPS IACUC is solely responsible for collecting and reviewing this information for projects involving the use of vertebrate animals in NPS units. The information collected is not available from any other source.

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

The collection of this data will not have any significant impacts on small businesses. The completion of any form is considered as part of normal business activities to conduct research.

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 we do not collect this information, the NPS would be in violation of the AWA and its Regulations. Specifically, the NPS would not have the information necessary to comply with their annual requirements to prepare a report for the USDA concerning the number and use of animals in the following categories:

(1) those being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.

(2) those upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.

(3) those upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs, or other effective relief methods were used.

(4) those upon which teaching experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests.

7. **Explain any special circumstances that would cause an information collection to be conducted in a manner:**

*** requiring respondents to report information to the agency more often than quarterly;**

*** requiring respondents to prepare a written response to a collection of information in fewer than 30 days after receipt of it;**

*** requiring respondents to submit more than an original and two copies of any document;**

*** requiring respondents to retain records, other than health, medical, government contract, grant-in-aid, or tax records, for more than three years;**

*** in connection with a statistical survey that is not designed to produce valid and reliable results that can be generalized to the universe of study;**

*** requiring the use of a statistical data classification that has not been reviewed and approved by OMB;**

*** that includes a pledge of confidentiality that is not supported by authority established in statute or regulation, that is not supported by disclosure and data security policies that are consistent with the pledge, or which unnecessarily impedes sharing of data with other agencies for compatible confidential use; or**

*** requiring respondents to submit proprietary trade secrets, or other confidential information, unless the agency can demonstrate that it has instituted procedures to protect the information's confidentiality to the extent permitted by law.**

There are no circumstances that require the information to be collected in a manner inconsistent with OMB guidelines.

8. **If applicable, provide a copy and identify the date and page number of publication 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 in response to the PRA statement associated with the collection over the past three years] and describe actions taken by the agency in response to these comments. Specifically address comments received on cost and hour burden.**

Describe 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. [Please list the names, titles, addresses, and phone numbers of persons contacted.]

Consultation with representatives of those from whom information is to be obtained or those who must compile records should occur at least once every 3 years — even if the collection of information activity is the same as in prior periods. There may be circumstances that may preclude consultation in a specific situation. These circumstances should be explained.

On April 22, 2022, a 60-day Federal Register notice (87 FR 24196) was published announcing this information collection. Public comments were solicited for 60 days ending June 21, 2022. We received two comments via email in response to that notice. We did not receive any comment on that notice. We reopened the comment period with a second notice published October 28, 2022 (87 FR 65245). This notice including information about a new electronic platform, *Key Solutions eProtocol IACUC Software Module for Animal Subjects* that was not described in the original notice. We receive the following comments for that notice.

The first commenter was concerned with the welfare of dogs, cats, and primates in lab research, none of which are included in the scope of the NPS IACUC. The NPS IACUC primarily reviews field and ecological research of North American wildlife, most often in free-ranging settings. The second comment was about the review process, not this specific information collection. The

commenter also suggested we add more language, definitions, and references regarding harm, pain, and distress to our forms.

NPS Response: In our response, we assured the commenter that our IACUC is well-situated to review the protocols we receive. We will also work towards incorporating additional language, definitions, and references regarding pain and distress in our communications with researchers.

The second comment did not address the information in the 60-day notice. We did not provide a response. Both comments received are attached in ROCIS as supplementary documents.

At the time of this submission, the electronic platform is currently under development and will not be in use before this collection expires. Therefore, the program is requesting an extension, without change to the currently approved collection. We will submit a request for revision when the electronic platform is operational

In addition to publishing the 60-day Federal Register notice, we actively solicited peer reviews from IACUC representatives, researchers who may need to submit the forms for review, and IACUC members and consultants who might review these forms. Overall the reviewers said that the website's instructions were easy to follow and that the forms were very straightforward. We did not change the content of the forms or the website, because the reviewers suggested that no changes or updates were necessary at this time. Based on their previous experiences with the IACUC process, the individuals listed below, provided suggestions and feedback concerning the structure, clarity of the procedure, and approximate length of time it would take to complete the forms.

Position	Affiliation
Biological Science Technician	National Park Service
Pacific West Regional Wildlife Biologist (NPS IACUC member)	National Park Service
Wildlife Veterinarian	U.S. Fish and Wildlife Service
Research Biologist & IACUC Co-Chair	U.S. Geologic Survey

“Whether or not the collection of information is necessary, including whether or not the information will have practical utility; whether there are any questions they felt were unnecessary.”

Respondent comment(s):

- Overall, the forms are well constructed, easy to understand, and complementary to each other in scope and length.
- The collection of this information is necessary and has practical utility.
- The set of forms comprises a thorough information capture system in terms of asking for the necessary elements of animal research that an IACUC needs to effectively help scientists ensure not only compliance but also implementation of best practices for animal welfare.
- These questions seem distilled from years of accumulated experience and touch upon critical review elements without gathering extraneous information.

NPS Response/Action Taken: None required.

“What is your estimate of the amount of time it takes to complete each form in order to verify the accuracy of our estimate of the burden for this collection of information?”

Respondent comment(s):

- General Submission form will take 1.5 – 5 hours to complete;
- Field Study Form will take 30 minutes – 1 hour;
- Concurrence form will take less than one hour;
- Annual Review form will take less than one hour; Amendment form will take less than one hour.

NPS Response/Action Taken: These estimates align with our current estimates and experiences of the researchers.

“Do you have any suggestions for us on ways to enhance the quality, utility, and clarity of the information to be collected?”

Respondent comment(s):

- Include brief descriptions/definitions of terms and form types at the top of forms to clarify which form needs to be completed.
- suggestions to rephrase questions to add clarity and to reduce redundancy.
- Ensure any links included are viable and current.
- The pdf forms contain lots of technical glitches in the coding (drop-down menus, logical flow, and dichotomous workflow structure, etc.).

NPS Response/Action Taken: We are working to fix the technical glitches in the pdf forms.

"Any ideas you might suggest which would minimize the burden of the collection of information on respondents?"

Respondent comment(s):

- Drop-down menus built into the forms could increase ease and speed of form completion.

NPS Response/Action Taken: We are working to include drop-down menus in the electronic forms.

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

We do not provide payment or gifts to respondents in this collection.

10. Describe any assurance of confidentiality provided to respondents and the basis for the assurance in statute, regulation, or agency policy.

We do not provide any assurance of confidentiality. Information is collected and protected in accordance with the Freedom of Information Act (FOIA) (5 U.S.C. 552). This collection will collect names and email addresses that will be used to follow up with respondents as needed. While no particular statements offering assurances of confidentiality are provided to the individual on the certification form, the NPS manages the forms in accordance with procedures established in the National Park Service System of Record INTERIOR/NPS-10 - Central Files — (86 FR 50156 September 7, 2021). No personally identifiable information will appear in the context of the results nor in any of our reports or findings.

The following information will be collected and stored:

- names, phone numbers, and emails for the researcher and any other personnel involved in the projects
- name, registration and permit numbers, protocol numbers, and contact information for other Institutional Animal Care and Use Committees associated with the project
- audiovisual recordings submitted in conjunction with forms for project activities
- confidential or proprietary information regarding the data collected and plans for use in future ventures

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. 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.

The collection does not include questions of a sensitive nature.

12. Provide estimates of the hour burden of the collection of information. The statement should:

*** Indicate the number of respondents, frequency of response, annual hour burden, and an explanation of how the burden was estimated. Unless directed to do so, agencies should not conduct special surveys to obtain information on which to base hour burden estimates. Consultation with a sample (fewer than 10) of potential respondents is desirable. If the hour burden on respondents is expected to vary widely because of differences in activity, size, or complexity, show the range of estimated hour burden, and explain the reasons for the variance. Generally, estimates should not include burden hours for customary and usual business practices.**

*** If this request for approval covers more than one form, provide separate hour burden estimates for each form and aggregate the hour burdens.**

*** Provide estimates of annualized cost to respondents for the hour burdens for collections of information, identifying and using appropriate wage rate categories. The cost of contracting out or paying outside parties for information collection activities should not be included here.**

Based on our administrative experiences plus the outreach described in item 8, we expect to receive 230 annual responses. The annualized respondent burden for this collection is estimated to be 140 hours. The frequency of response will be on occasion or as needed. Listed is average completion time for each form below:

- **General Submission form** - 3 hours
- **Field Study form** - 1 hour
- **Concurrence form** - 15 minutes
- **Amendment form** - 15 minutes
- **Annual Review form** - 15 minutes.

Because of the differences in user familiarity and the amount of information provided in each form, as well as the time it takes for individual computer systems to make the connection with our website we expect slight variations in the time to complete each form. The data entry level sought is the same as used in most computer operating programs (no advanced knowledge,

training, or expertise is required). For the respondents reporting more than one species per report the additional time is calculated in the average time to complete the form.

Table 12.1. Estimated Annual Burden Hours

Respondent	Annual Number of responses	Completion Time per form	Total Burden (hours)*
State and Local Agencies			
Form 10-1301 - General Submission Form	14	3 hours	42
Form 10-1301A - Amendment Form	10	15 mins	3
Form 10-1302 - Annual Review Form	55	15 mins	14
Form 10-1304 - Field Study Form	10	1 hour	10
Form 10-1303 - Concurrence Form	41	15 mins.	10
Subtotal	***0***		79

	Annual Number of responses	Completion Time per form	Total Burden (hours)*
Colleges, Universities, and Non-Profits			
Form 10-1301 - General Submission Form	10	3 hours	30
Form 10-1301A - Amendment Form	10	15 mins	3
Form 10-1302 - Annual Review Form	40	15 mins	10
Form 10-1304 - Field Study Form	10	1 hour	10
Form 10-1303 - Concurrence Form	30	15 mins	8
Subtotal	***100***		***61***

TOTAL	**230**		**140**

**The calculations in the table are rounded up to the nearest whole number.*

We estimate that we will receive 230 annual responses totaling 140 annual burden hours (Table 12.1). We estimate the dollar value of the burden hours to be **$7,004** (rounded). We used the rates listed below in accordance with the Bureau of Labor Statistics (BLS) News Release (USDL-23-0488) December 2022 Employer Costs for Employee Compensation (released March 17, 2023). The particular values utilized are:

- States and Local Agencies: Table 3 lists the total compensation as $57.60, including benefits
- Private Businesses (e.g., non-profit and Private Universities): Table 4 lists the total compensation as $40.23, including benefits.

Table 12.2 Estimated Dollar Value of Annual Burden Hours

Sector	Total Annual Number of Responses	Total Annual Burden Hours	Dollar Value of Burden Hours (Including Benefits)	Total Dollar Value of Annual Burden Hours
Federal, State, and Local Agencies	130	79	$57.60	$4,550
Colleges, Universities, and Non-Profits	100	61	$40.23	$2,454
TOTAL	**230**	**0**		**0**

13. Provide an estimate of the total annual non-hour cost burden to respondents or recordkeepers resulting from the collection of information. (Do not include the cost of any hour burden already reflected in item 12.)

* **The cost estimate should be split into two components: (a) a total capital and start-up cost component (annualized over its expected useful life) and (b) a total operation and maintenance and purchase of services component. The estimates should take into account costs associated with generating, maintaining, and disclosing or providing the information (including filing fees paid for form processing). Include descriptions of methods used to estimate major cost factors including system and technology acquisition, expected useful life of capital equipment, the discount rate(s), and the time period over which costs will be incurred. Capital and start-up costs include, among other items, preparations for collecting information such as purchasing computers and software; monitoring, sampling, drilling and testing equipment; and record storage facilities.**
* **If cost estimates are expected to vary widely, agencies should present ranges of cost burdens and explain the reasons for the variance. The cost of purchasing or contracting out information collection services should be a part of this cost burden estimate. In developing cost burden estimates, agencies may consult with a sample of respondents (fewer than 10), utilize the 60-day pre-OMB submission public comment process and use existing economic or regulatory impact analysis associated with the rulemaking containing the information collection, as appropriate.**
* **Generally, estimates should not include purchases of equipment or services, or portions thereof, made: (1) prior to October 1, 1995, (2) to achieve regulatory compliance with requirements not associated with the information collection, (3) for reasons other than to provide information or keep records for the government, or (4) as part of customary and usual business or private practices.**

There is no non-hour cost burden to applicants resulting from this collection. There are no fees associated with this process or requirements.

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.

The estimated annual cost to the Federal Government is $769,179. This includes the cost to the Federal Government for salaries and benefits for administering this information collection ($766,679) as shown below in Table 14.1 and operational expenses ($2,500) as shown in Table 14.2. We used the Office of Personnel Management Salary Table 2023-DEN (to determine the hourly rate. We multiplied the hourly rate by 1.5 to account for benefits (as implied by the BLS news release USDL-23-0488 mentioned above).

Table 14.1: Annual Cost to the Federal Government

Position	Grade/ Step	Hourly Rate	Hourly Rate incl. benefits (1.59 x hourly pay rate)	Estimated time (hours)	Total Annual Cost
IACUC Administrator	GS 7/5	$28.09	$44.66	1,664	$74,314
NPS Veterinarian	GS 13/5	$59.25	$94.21	1,664	$156,765
IACUC Committee Members ***(x13)***	GS 12/5	$49.83	$79.23	520	$535,600
				Total	0

Table 14.2: Operational Expenses

Operational Expenses	Estimated Cost
Contract Support for website oversight, database management, and maintenance	$2,500

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

There are no changes or adjustments

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.

The information collected will not be tabulated or published for statistical use. The forms will be stored in a database to maintain documentation of approved proposals.

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.

We will display the OMB control number and expiration date on all information collection instruments and the website.

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

There are no exceptions to the certification statement.