

Supporting Statement A

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

OMB Control Number 1024--0265

Terms of Clearance: None.

General Instructions

A completed Supporting Statement A must accompany each request for approval of a collection of information. The Supporting Statement must be prepared in the format described below, and must contain the information specified below. If an item is not applicable, provide a brief explanation. When the question "Does this ICR contain surveys, censuses, or employ statistical methods?" is checked "Yes," then a Supporting Statement B must be completed. OMB reserves the right to require the submission of additional information with respect to any request for approval.

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.

Principal Investigators (PI) are required to submit one of the following forms for consideration by the committee:

- The NPS IACUC General Submission (GS) form

- The NPS IACUC BioBlitz/Field Study form
- The NPS IACUC Concurrence Review form
- The NPS IACUC Amendment form
- The NPS IACUC Annual Review form

As determined by the AWA, The NPS Institutional Animal Care and Use Committee (NPS IACUC), is a self-regulating entity that currently consists of a Chair and two additional posts (a veterinarian to serve as the “Attending Veterinarian” and another individual to serve as the “Unaffiliated Member At-Large”).

Relevant Legislation:

- ***Animal Welfare Act Regulations*** 7 U.S.C. 2131-2159; **§2.31, d, 1**
“the IACUC shall conduct a review of those components of the activities related to the care and use of animals and determine that the proposed activities are in accordance with this subchapter unless acceptable justification for a departure is presented in writing...”
- ***NPS Organic Act, 16 U.S.C. §a-1***
“...which purpose is to conserve the scenery and the natural and historic objects and the wild life therein and to provide for the enjoyment of the same in such manner and by such means as will leave them unimpaired for the enjoyment of future generations”.

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 uses 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. Review of a new General Submission or Concurrence form is required every three years 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, and for 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 Animal Welfare Act, 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 (PDF), unless a deviation is justified for scientific reasons in writing by the investigator.

1. *The General Submission form*: This form has been revised to better reflect the information required under animal welfare law and policies by explaining and providing examples of literature search strategies for alternatives to procedures that may cause pain and distress to the animals. This form will require the following information:

- A project narrative which includes: the title, a statement of the objectives to be addressed, scope of the proposed project, literature review for alternatives to potentially painful or distressful procedures, 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.
- 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 Animal Welfare Act, its Regulations, and the Interagency Research Animal Committee.

2. *The Concurrence and BioBlitz/Field Study forms:* These are two new forms that will be 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 which includes: the title, a statement of the objectives to be addressed, 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 Animal Welfare Act, its Regulations, and the Interagency Research Animal Committee.

3. *The Amendment and Annual Review forms:* Both of these 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.
- These forms were modified to request details regarding any adverse or unexpected consequences that may have occurred during approved activities involving animals and proposing changes to avoid further incidents.

- For annual reviews, changes were made to the form to collect details on the actual numbers, species, and level of pain or distress experienced by the animals should be included in order for the NPS IACUC to accurately report this information to the United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), Animal Care program at the end of each fiscal year.
- A signed declaration of compliance with the procedures and methods outlined in The Animal Welfare Act, its Regulations, and the Interagency Research Animal Committee.

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

The forms in ICR that were previously only available as a Word document, has now been modified to be a fillable pdf format. The forms have been reviewed and are in compliance with the current 508 standards. Each form has received a form number from the NPS Forms officer.

Electronic submission is strongly encouraged through the program's website (<http://www1.nrintra.nps.gov/brmd/wildlifehealth/iacuc/>). Respondents can also print the forms from the same website and submit by way of regular mail. We expect that 90% of the respondents will use the electronic submission option and 10% will continue to submit via paper copies.

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.

The NPS Institutional Animal Care and Use Committee is solely responsible for collecting and reviewing this information for projects involving the use of vertebrate animals in NPS units. The information that we collect is not available from any other source, The Concurrence forms (A2), require the researchers to submit a copy of an approved form from their primary institution outside of the NPS as a way to minimize duplication.

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 will be considered a part of normal business activities to conduct research. In most cases the number of business is no more than two businesses (the only known business impacted included two ranchers)

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 Animal Welfare Act 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 January 13, 2016, a 60-day Federal Register notice (81 FR 1642) was published announcing this information collection. Public comments were solicited for 60 days ending March 14, 2016. We did not receive any comments in response to that notice.

However, in addition to publishing the 60 day Federal Register notice we actively solicited peer reviews from former IACUC participants, to provide feedback about each of the forms. We asked them to provide feedback about the clarity of instruction and the estimated time to complete a prototype of an on-line version of the forms. 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. 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. The respondents concurred with our estimated burden time needed would be 3 hours to complete the General Submission form; 1 hour to complete the BioBlitz/Field Study form; 15 minutes to complete the Concurrence form; 30 minutes to complete the Amendment form; and 15 minutes to complete the Annual Review form. These estimates reflect the time it will take each applicant to prepare the narrative and provide the additional background information needed to complete the application.

Reviewer# 1	Richard Husser IACUC Director University of Colorado, Boulder (303) 492-8187
Reviewer# 2	Robert Sikes, Ph.D. Associate Professor University of Arkansas-Little Rock (501) 569-3516
Reviewer #3	Patrice Klein, MS, VMD, DACPV, DACVPM Attending Veterinarian United States Department of Agriculture, United States Forest Service (202) 365-9359
Reviewer #4	Samantha Gibbs, DVM, Ph.D. Wildlife Veterinarian United States Fish and Wildlife Service (571) 216-5776

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 assurances of confidentiality, however, the Department of the Interior is required under Section 208 of the E-Government Act of 2002 (Public Law 107-347, 44 U.S.C. Chapter 36) to conduct a Privacy Impact Assessment (PIA) before developing or initiating new information collections that use information technology (IT), that collects, maintains or disseminates personally identifiable information (PII). The NPS is currently awaiting the approval of a Privacy Impact Assessment (PIA) and the issuance of a System of Records Number (SORNs) for this collection.

When a person visits this web site and submits the forms, that information will be stored in a secure database. We must retain personally identifiable information in order to correspond with the respondent and to provide a response from the committee concerning their request. We will never use individual profiles for commercial marketing or any purposes other than for the submission of these forms.

The following information may be stored: names, phone numbers, and emails for the researcher and any other personnel involved in the projects; name, registration 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. This information will not be used for associating patterns of site navigation with individual users.

- 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 a total of 230 annual responses. We estimate that it will take an average of 3 hours to complete the General Submission form; 1 hour to complete the BioBlitz/Field Study form, 15

minutes to complete the Concurrence Form, 15 minutes to complete the Amendment form; and 15 minutes to complete the Annual Review form, totaling 135 burden hours.

Variations can be expected in the reporting burden for completion of the forms in this collection because of the differences in user familiarity and the amount of information provided in each form and the time it takes for individual computer systems to make the connection with our website. The data entry level sought is the same as used in most computer operating program (no advanced knowledge, training, or expertise is required). For the respondents reporting more than one species per report the additional time has been considered in the average time it takes to complete the form.

Table 1. Estimated Annual Burden Hours

Respondent and forms	Annual Number of respondents	Completion Time Per form	Total Burden (hours)*
State and Local Agencies			
General Submission Form	14	3 hours	42
Amendment Form	10	15Mins	3
Annual Review Form	55	15 Mins	14
BioBlitz/Field Study Form	10	1 hour	10
Concurrence Form	41	15 Mins.	10
Subtotal	130		79
Private (non-profit)			
General Submission Form	10	3 hours	30
Amendment Form	10	15 Mins	3
Annual Review Form	40	15 Mins	10
BioBlitz/ Field Study Form	10	1 hour	10
Concurrence Form	30	15 Mins	8
Subtotal	100		61
TOTAL	230		140

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

We estimate the total dollar value of the annual burden hours to be \$7,690 (Table 2). The estimated dollar value of the burden hours for this collection takes into account the nature of our respondents state and local government agencies and Private businesses, (this includes university and non-profit employees). This estimated dollar value included the multiplier for benefits and is based on the National Compensation Survey: Occupational Wages in the United States published by the Bureau of Labor Statistics Occupation and Wages, (BLS news release USDL-16-0463for Employer Costs for

Employee Compensation—December 2015 at <http://www.bls.gov/news.release/ecec.nr0.htm> - Released March 10, 2016). The particular values utilized are:

States and Local Agencies: Average hourly wage is \$35.87 multiplied by 1.51 to account for total benefits (\$54.16). To obtain the rate for State and local government, we used data from <http://www.bls.gov/news.release/ecec.t03.htm> - Table 3.

Private Businesses (e.g., non-profit and Private Universities): Average hourly wage is \$38.75 multiplied by 1.44 to account for total benefits (\$55.92). To obtain the rate for professionals in the private sector we used data from <http://www.bls.gov/news.release/ecec.t05.htm> -Table 5.

Table 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
State and Local Agencies	130	79	\$54.16	\$4,279
Private Businesses (non-profit and Private Universities)	100	61	\$55.92	\$3,411
TOTAL	230	140		\$7,690

**The calculations in this table are rounded up to the nearest whole dollar amount.*

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 total annual cost to the Federal Government is \$221,536. This includes the cost to the Federal Government for salaries and benefits for administering this information collection \$211,536 and operational expenses \$2,500. Table 3 below shows Federal staff and grade levels associated with this information collection. We used the Office of Personnel Management Salary Table 2016-DEN (https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2016/DEN_h.pdf) to determine the hourly rate. We multiplied the hourly rate by 1.5 to account for benefits (as implied by the BLS news release 10-10-0774 mentioned above). Operational expenses are listed in Table 4 below.

Table 3: Annual Cost to the Federal Government

Position	Grade/ Step	Hourly Rate	Hourly Rate incl. benefits (1.5 x hourly pay rate)	Estimated time (hours)	Cost per federal staff (Hourly Pay Rate incl. Benefits)
IACUC Administrator	GS 7/5	\$23.37	\$35.05	1,664	\$58,323
NPS Veterinarian	GS 12/4	\$40.24	\$60.36	1,664	\$100,439
IACUC Committee Member	GS 12/4	\$40.24	\$60,36	520	\$31,387
IACUC Committee Member	GS 12/4	\$40.24	\$60.36	520	\$31,387
Total					\$221,536

Table 4: Operational Expenses

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

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

This is a renewal of a currently approved collection. The program changes include the following adjustments listed in the table below.

Respondent and forms	Previously Approved		Current Request		Program Change due to Agency Estimate	
	Annual Number of respondents	Time Burden (hours)	Annual Number of respondents	Time Burden (hours)	Annual Number of respondents	Time Burden (hours)
State and Local Agencies						
General Submission Form	65	195	14	42	-51	-153
Amendment Form	30	8	10	3	-20	-5
Annual Review Form	30	5	55	14	+25	+9
Exhibitor Form	15	45	REMOVED		-15	-45
BioBlitz/Field Study Form	0	0	10	10	+10	+10
Concurrence Form	0	0	41	10	+41	+10
Subtotal	140	253	130	79	-10	-174
Private (non-profit)						
General Submission Form	25	75	10	30	-15	-45
Amendment Form	10	3	10	3	0	0
Annual Review Form	10	2	40	10	+30	+8
Exhibitor Form	5	15	REMOVED		-5	-15
BioBlitz/ Field Study Form	0	0	10	10	+10	+10
Concurrence Form	0	0	30	8	+30	+8
Subtotal	50	95	100	61	50	-34
TOTAL	190	348	230	140	40	-208

1. Modifications to the General Submission, Amendment, and Annual Review Forms, resulted in an overall net decrease of 31 respondents and a net decrease of 186 hours from our previously approved request for these forms.

2. The discontinued use of the exhibitor's form, due to clarification in the scope and responsibilities of the IACUC oversight of activities in NPS units which do not extend to exhibition activities. This caused program change with decreased the overall number of respondents by 20 respondent and the burden by 60 hours.

3. The addition of the new Concurrence Form and Field Study/BioBlitz Forms added 91 new respondents and 38 new burden hours.

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.