



**UNITED STATES NATIONAL PARK SERVICE
INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE
(NPS IACUC)
STANDARD OPERATING PROTOCOL**

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STANDARD OPERATING PROTOCOL

SECTION ONE: INTRODUCTION

§ 1.1: General Aspects of the NPS IACUC

§ 1.1 (a): Mandate of the NPS IACUC

The NPS IACUC derives both its mandate and purpose from the Animal Welfare Act (AWA) and its Regulations (AWAR): § 2.31 (a) of the AWAR: *“The Chief Executive Officer of the research facility shall appoint an Institutional Animal Care and Use Committee (IACUC), qualified through the experience and expertise of its members to assess the research facility’s animal program, facilities, and procedures”*. The NPS in its entirety is registered with the United States Department of Agriculture Animal Plant Health Inspection Service Animal Care unit (USDA APHIS AC) as a single research institution.

§ 1.1 (b): Functions of the NPS IACUC

The NPS IACUC (the Committee) derives its functions from the following AWAR: AWAR § 2.31 (c) (abbreviated): *“IACUC functions. With respect to activities involving animals, the IACUC, as an agent of the research facility shall: (1) Review the research facility’s program for humane care and use of animals, (2) Inspect all of the research facility’s animal facilities...except free-living wild animals in their natural habitat need not be included in such inspections, (3) Prepare reports of its evaluations...and submit them to the Institutional Official (IO) of the research facility, (4) Review, and if warranted, investigate concerns involving the care and use of animals at the research facility resulting from public complaints received and from reports of noncompliance received from laboratory or research facility personnel or employees, (5) Make recommendations to the IO regarding any aspects of the research facility’s animal program, facilities, or personnel training, (6) Review and approve, require modifications in (to secure approval), or withhold approval of those components of proposed activities related to the care and use of animals, (7) Review and approve, require modifications in (to secure approval), or withhold approval of proposed significant changes regarding the care and use of animals in ongoing activities, and (8) Be authorized to suspend an activity involving animals”*. Moreover, the AWAR defines the term “Research Facility” as such: AWAR § 1.1 (abbreviated); *Research Facility means any school (except an elementary or secondary school), institution, organization, or person that uses or intends to use live animals in research, tests, or experiments, and that (1) purchases or transports live animals in commerce, or (2) receives funds under a grant, award, loan, or contract from a department, agency, or instrumentality of the United States for the purpose of carrying out research, tests, or experiments..* The NPS IACUC registration with the USDA APHIS AC recognizes the entirety of the NPS as a single research facility. This is to say that any use of vertebrate animals (e.g. research, teaching, and/or exhibition) on NPS territory is by design taking place in the USDA APHIS AC-registered NPS research facility, and is thus under the jurisdiction of the NPS IACUC.

§ 1.1 (c): Purpose of the NPS IACUC

The NPS IACUC purpose is threefold: 1.) To assure NPS compliance with the AWA and AWAR. Through the execution of the abovementioned AWAR-mandated IACUC functions, the NPS IACUC will ensure that activities involving the use of vertebrate animals in NPS units comply with the AWAR and the Interagency Research Animal Committee (IRAC); 2.) To facilitate –through the promotion of animal welfare- the highest possible standards of science and natural resource stewardship in the NPS; and 3.) To facilitate continuing education and training with regard to the AWA, the AWAR, the IRAC, and general issues of animal welfare.

§ 1.1 (d): Adherence to the Interagency Research Animal Committee Principles

As a federal agency, the NPS IACUC voluntarily ensures that the NPS upholds the “*Government Principles for the Utilization and Care of Vertebrate Animals Used in Teaching, Research, and Training*”, as laid forth by the Interagency Animal Research Committee and the National Resource Council (*see appendix A*). Herein following, any reference made in this document referring to NPS IACUC adherence/compliance to the AWA and/or AWAR shall also include and intend reference to, adherence to the IRAC. In other words, statements in this document alluding to AWA/AWAR compliance infer IRAC compliance as well.

§ 1.1 (e): Jurisdictional Authority of the NPS IACUC

As a federally registered IACUC with the USDA APHIS AC, the NPS IACUC is recognized as the sole IACUC representing and serving the NPS. Because of this fact, the jurisdictional extent of the NPS IACUC recognized by the USDA APHIS AC encompasses all territories and units of the NPS. *See also § 1.1 (b): Functions of the NPS IACUC.*

§ 1.1 (f): The NPS Institutional Official (NPS IO)

As mandated by the AWAR, research facilities must have an Institutional Official to guarantee legal responsibility that AWA/AWAR compliance will be met. AWAR § 1.1 Institutional Official: “*The individual at a research facility who is authorized to legally commit on behalf of the research facility that the requirements of CFR parts 1, 2, and 3 will be met*”. Regarding the NPS, the post of NPS IO is held by whomever serves as the sitting NPS Deputy Director, Operations. When or if the NPS Deputy Director, Operations retires, resigns, or leaves office for any reason, their replacement will assume the post of NPS IO following appropriate notification to the USDA APHIS AC.

§ 1.1 (f) (1): Functions of the NPS IO. The duties and responsibilities of the NPS IO are presented in multiple sections of the AWAR, (*see Appendix B*). General duties of the NPS IO (in addition to that previously stated) include signing official NPS IACUC registration with the USDA APHIS AC, signing and submitting the NPS IACUC annual report to Congress, and coordinating membership to the NPS IACUC (e.g. receiving nominations and making final decisions regarding invitations for membership). Refer to Appendix B for a complete list of duties and responsibilities of the NPS IO.

§ 1.1 (f) (2): The NPS IO Administrator (NPS IOA). In order to facilitate the duties and responsibilities of the post, the office of the NPS IO has an administrator to assist with the workload. As the NPS IO is a secondary duty of the NPS Deputy Director, Operations, the NPS IOA can represent/substitute for the NPS IO in most capacities except those requiring the official attentions of the NPS IO. Under approval by, and on behalf of the NPS IO, the NPS IOA has the authority to receive, handle, provide comment on, and present both official and unofficial

documents from the NPS IACUC (Chair), the USDA APHIS AC, and third parties; consult with the NPS IACUC (Chair), the USDA APHIS AC, and third parties; and generally serve in any capacity deemed necessary by the NPS IO. The NPS IOA does not have the authority of signature, approval, or rejection of any documents or policies reserved for the NPS IO. The NPS IOA exists to assist the NPS IO, and to facilitate communication between and among the NPS IO, the NPS IACUC, the USDA APHIS AC, and third parties. The NPS IOA is appointed by the NPS IO.

§ 1.1 (f) (3): The NPS IO Deputy Administrator (NPS IODA). The NPS IODA serves in a parallel capacity to that of the NPS IOA, has identical authority to that of the NPS IOA when called upon, and is likewise appointed by the NPS IO. However, the NPS IODA directly supports the NPS IO and the NPS IOA. The NPS IODA acts in place of the NPS IOA when called upon to do so.

§1.2: Composition of the NPS IACUC

§1.2 (a): Selection, Nomination, and Invitation of Members

Membership of the NPS IACUC is determined by the NPS IO. Sections 2.31 (a) and (b) of the AWAR state, “*The Chief Executive Officer (CEO) of the research facility shall appoint an Institutional Animal Care and Use Committee (IACUC), qualified through the experience and expertise of its members to assess the research facility’s animal program, facilities, and procedures*”. *The members of each Committee shall be appointed by the Chief Executive Officer of the research facility*”. In order to maximize practicality, the office of NPS Deputy Director, Operations is identified as the operative CEO for Animal Welfare in the NPS, and therefore serves as the NPS IO.

Regarding NPS IACUC membership protocol, the process is as follows: 1.) Individual NPS Regions submit membership nominations and any accompanying justifications and/or supporting documentation to the office of the NPS IO. 2.) After having received the aforementioned, the NPS IO evaluates all submitted nominations. The NPS IO may seek consultation with the NPS IACUC Chair, other NPS IACUC members, or anyone else deemed relevant in evaluating nominees; however, final decisions regarding NPS IACUC membership are reserved for the NPS IO. Nominees will be evaluated based upon AWAR guidelines in §2.31 (a), (*see above*). 3.) Nominees will then be selected, and officially invited –in writing- by the NPS IO to become members the NPS IACUC. Should an invitee decline this invitation to join the NPS IACUC, the NPS IO will either revisit the nomination pool from the declining invitee’s region, or request a new nomination be submitted from the region in question.

§1.2 (b): Regional Directorships

Regional directorships respond directly to the NPS IO-initiated call for NPS IACUC membership, and by so doing ensure NPS IACUC representation from their respective regions. Using the criteria in AWAR §2.31 (a), regional directorships gather, choose, and submit regional nominees for NPS IACUC membership to the NPS IO every three years/per term, or as needed.

§1.2 (c): AWAR-Mandated Membership

There are three AWAR-mandated membership posts on the NPS IACUC. Section 2.31 (b) (2), (3) (i) and (3) (ii) of the AWAR states, “*The Committee shall be composed of a Chairman and at least two additional members; Of the members of the Committee: At least one*

shall be a Doctor of Veterinary Medicine, with training or experience in laboratory animal science and medicine, who has direct or delegated program responsibility for activities involving animals at the research facility; At least one shall not be affiliated in any way with the facility other than as a member of the Committee, and shall not be a member of the immediate family of a person who is affiliated with the facility. The Secretary intends that such person will provide representation for general community interests in the proper care and treatment of animals”. Per the language of the AWAR, the three mandated posts of the NPS IACUC are the Chair, the Attending Veterinarian, and the Unaffiliated Member At-Large. As dictated by necessity, one person may serve in multiple capacities regarding the aforementioned AWAR-mandated posts; e.g. the same person may serve as both Chair and Attending Veterinarian; however, such conditions should be temporary, and every attempt made to retain a one post - one person model in order to duly balance both the workload of the respective posts and any potential (albeit unintentional) bias that could result from such a situation.

§1.2 (c) (1): The NPS IACUC Chair. The primary functions of the Chair are to serve as lead and chief point of contact for the Committee, facilitate Committee functions, organize the day-to-day business and logistics of the Committee, and serve as a voting member of the Committee. The Chair has a three-year term, which is extendable indefinitely; i.e. there is no limit to the number of extensions. The NPS IACUC Chair duties are enumerated in Appendix C.

§1.2 (c) (2): The NPS IACUC Attending Veterinarian. The primary function of the Attending Veterinarian (AV) is to direct the care and use of animals in the NPS. The AV, as a trained veterinarian, provides veterinary medical expertise to the NPS IACUC and facilitates its decisions regarding all protocols involving the handling of animals in NPS units. Pertaining to project review, section 2.31 (d) (1) (iv) (B) of the AWAR states that an IACUC must, “*Involve, in their planning, consultation with the attending veterinarian or his or her designee*”. The NPS AV can delegate his or her authority to anyone he or she designates as appropriate to do so; e.g. in cases wherein the project under assessment is geographically distant, and on-site assessment by the sitting AV is impractical, the AV may choose to delegate his or her authority to another, local veterinarian in the vicinity of the project locale. The AV has a three-year term, which is extendable indefinitely; i.e. there is no limit to the number of extensions. The AV is a voting member of the NPS IACUC. The NPS IACUC AV duties are enumerated in Appendix D.

§1.2 (c) (3): The NPS IACUC Unaffiliated Community Member At-Large. The primary function and mandate of the NPS IACUC Unaffiliated Member are clearly stated in section 2.31 (b) (3) (ii) of the AWAR, “*At least one shall not be affiliated in any way with the facility other than as a member of the Committee, and shall not be a member of the immediate family of a person who is affiliated with the facility. The Secretary intends that such person will provide representation for general community interests in the proper care and treatment of animals*”. The NPS IACUC Unaffiliated Member (NPS IACUC UMAT) serves the interest of the extended community outside the NPS, and is relied upon to provide the NPS IACUC with perspective and insight, the character of which might be otherwise unapparent to NPS personnel. The UMAT has a three-year term, which is extendable indefinitely; i.e. there is no limit to the number of extensions. The NPS IACUC UMAT is a voting member of the NPS IACUC. The NPS IACUC UMAT duties are enumerated in Appendix E.

§1.2 (d): Non-AWAR- Mandated Membership

The AWAR neither describes nor limits IACUC membership above and/or beyond the aforementioned mandated membership. Thus, NPS IACUC membership in addition to the AWAR-mandated minimum is optional and principally organized by NPS region. Each NPS region has two representatives; nominated by their respective regional directorate and approved by the NPS IO. Each region has one seat on the NPS IACUC held by a primary voting representative and supported by an alternate to act in the primary's stead in the case of his/her absence.

§1.2 (e): The NPS IACUC Administrator

In order to facilitate the duties and responsibilities of the Committee, the NPS IACUC has an administrator to assist with the workload. The NPS IACUC Administrator exists to support the NPS IACUC Chair (and other Committee members) in most capacities except those requiring the official attentions of the NPS IACUC. Under approval by, and on behalf of the NPS IACUC, the NPS IACUC Administrator has the authority to receive, handle, organize, and present both official and unofficial documents to and from the NPS IACUC (Chair), the USDA APHIS AC, the NPS IO, and third parties; collaborate with the NPS IACUC (Chair), the USDA APHIS AC, the NPS IO, and third parties; and generally serve in any capacity deemed necessary by the NPS IACUC Chair. The NPS IACUC Administrator does not have the authority of signature, approval, or rejection of any documents or policies reserved for the NPS IACUC. The NPS IACUC Administrator exists to assist the NPS IACUC, and to facilitate communication between and among the NPS IACUC, the NPS IO, the USDA APHIS AC, and third parties. The NPS IACUC Administrator is appointed by the NPS IACUC Chair.

§1.2 (f): Selection, Nomination, and Invitation of Alternate Members

Alternate members of the NPS IACUC are selected, nominated, and invited to serve in the same fashion as those chosen for full-time membership. Individuals nominated for alternate status are identified as such on their individual nomination submissions to the NPS IO. NPS IACUC alternate members assume active, full-time membership duties at the discretion of a requesting full-time member from their region, or as circumstances dictate; e.g. in surrogate by request of the NPS IACUC Chair to achieve a quorum, or conduct an inspection. Alternates may serve on active, full-time status as long as they are needed to do so, or as long as practicality demands. Alternates may be promoted to full-time status with approval of the NPS IO.

SECTION TWO: OPERATIONS

§2.1: NPS IACUC Compliance Protocols

§2.1 (a): Project Review

The NPS IACUC defines a “project” as any activity involving the use of vertebrate animals in one or more NPS units, and is inclusive of research, teaching, and exhibition. Moreover, it is the directive of the NPS IACUC to assess AWAR compliance in projects taking place in NPS units. Assessment of projects for AWAR compliance is carried out by a systematic process of review.

§2.1 (a) (1): Full Committee Review. Section 2.31 (d) (2) of the AWAR states, “*If a full Committee review is requested for a proposed activity, approval of that activity may be granted only after review, at a convened meeting of a quorum of the IACUC, and with the approval vote of a majority of the quorum present*”. Full Committee Review (FCR) is the one of three possible methods of initial NPS IACUC project review. Upon receipt of a project submission for review, the submission –in its entirety- will be distributed to the full Committee. In the case of an FCR, each Committee member is expected to perform an in-depth study of the project submitted, and become familiar with any and all aspects of the project, especially regarding those involving animal care and handling. Communication during this pre-review period is encouraged, especially among Committee members and between Committee members and the submitting project principle investigator (PI). Members should conduct such project pre-reviews prior to a convened meeting of the NPS IACUC. The pre-review period is designed to expedite project discussion and voting during official NPS IACUC meetings; i.e. by the time of the meeting, it is expected that projects on the agenda should have already undergone exhaustive examination, and thus be ready for a vote with minimal discussion. Projects are approved, rejected, or referred back to the PI for further alterations by a majority of a quorum of the NPS IACUC in real time. The process of FCR pertains to projects involving research, teaching, and exhibition.

§2.1 (a) (2): Designated Member Review. Section 2.31 (d) (2) of the AWAR states, “*If full Committee review is not requested, at least one member of the IACUC, designated by the Chairman and qualified to conduct the review, shall review those activities, and shall have the authority to approve, require modifications in (to secure approval), or request full Committee review of any of those activities*”. At the discretion of the Chair, Designated Member Review (DMR) may be carried-out by one or more NPS IACUC members. Following receipt of a project for review, any member or members of the NPS IACUC may also request a DMR on that particular project. These options constitute the other two possible methods of initial NPS IACUC project review. The option of DMR is chiefly relevant in light of regional NPS IACUC representation, as the member or members representing a particular region may reserve priority status for review of projects emanating from, or primarily involving their region. The Chair can also initiate a standing DMR for any region; i.e. establish a running or continuous DMR for regional representatives to have priority of review over any and all projects in their region. Projects reviewed under DMR protocol are the exclusive domain of the assigned DMR member or members; i.e. the reviewing member or members are responsible for all aspects of review pertaining to that project; e.g. communications, notifications to the PI, and final organization of the project in the official NPS IACUC files.

§2.1 (a) (3): Consultation. Section 2.31 (d) (3) of the AWAR states, “*The IACUC may invite consultants to assist in the review of complex issues arising out of its review of proposed activities. Consultants may not approve or withhold approval of an activity, and may not vote with the IACUC unless they are also members of the IACUC*”. In the course of project review – whether by FCR or DMR- NPS IACUC members may engage the opinions and advise of professional consultants in order to ensure the highest possible standards of informed review.

§2.1 (a) (4): Submissions. Projects involving the use of vertebrate animals in NPS units may require NPS IACUC review prior to the commencement of activities. Such projects must be submitted to the NPS IACUC in an organized fashion, and in such a way as to greatly facilitate a timely review process without compromising the requirements of the AWAR.

§2.1 (a) (4) A: Forms

In order to ensure a timely and thorough review process, the NPS IACUC must provide a set of forms to guide the submitter throughout. There are four key points in the life of a project as it passes through the NPS IACUC review system; e.g. the initial submission, any possible addenda, renewal, and follow-up. Each of these key points in the review process must be facilitated by a form, specific to the terms, needs, and regulations required at that respective point in the process. No final and/or permanent version can exist for any of the aforementioned forms, as flexibility and the ability to evolve with developing interpretations of the AWAR must be cornerstones of the NPS IACUC program. However, each of the forms must –by design- elicit concise, relevant, and plausible responses from the submitter in order that his or her project receive proper AWAR assessment in the most just, and expedient manner possible. The NPS IACUC must also employ a fifth form, covering research facility inspections. And like the aforementioned project review forms, this form must be designed to expedite a thorough and proper AWAR assessment of any given NPS research facility. Currently operational versions of all NPS IACUC forms are appended to this document.

§2.1 (a) (4) B: The Review Process

The NPS IACUC review process consists of several distinct parts. Projects undergoing review for the first time (initial submission) receive a preliminary review and classification based upon the character of their design. Moreover, approved projects may also be amended, and all approved projects carried-out over multiple years must be renewed annually followed by a total resubmission prior to the start of their fourth year.

§2.1 (a) (4) B.1: Preliminary Review. Projects undergoing first-time review receive a preliminary review in order to establish NPS IACUC jurisdictional authority. Projects deemed to fall under the jurisdiction of the NPS IACUC are Category A projects. Projects deemed to fall outside the jurisdiction of the NPS IACUC are Category B projects.

§2.1 (a) (4) B.2: Classification. Projects assessed as Category A are further classified based upon AWAR guidance, and whether or not they have received prior review and/or approval from an IACUC other than the NPS IACUC.

- **§2.1 (a) (4) B.2.a: Subcategory A1.** Projects involving the use of vertebrate animals in NPS units that are judged by the NPS IACUC to cause no harm, involve no invasive procedures, and do not materially alter the behavior of animals under study are deemed to be *Field Studies* per the language of the AWAR, and are classified by the NPS IACUC as Subcategory A1 projects. Subcategory A1 projects do not require official NPS IACUC review; however, the NPS IACUC reserves the right monitor such projects as needed. Examples of such projects might range from one that involves the distant observation of animals with no interaction whatsoever, to a project that briefly handles and releases

animals with no appreciable harm, invasive procedures, or material alteration of behavior as deemed so by the NPS IACUC.

- **§2.1 (a) (4) B.2.b: Subcategory A2.** Projects involving the use of vertebrate animals in NPS units that have undergone AWAR review, and have received approval from, an accredited USDA APHIS AC or NIH OLAW (properly) registered IACUC other than the NPS IACUC, are recognized by the NPS IACUC as legitimate projects and need not undergo duplicate review by the NPS IACUC. Such projects are classified by the NPS IACUC as Subcategory A2 projects. Subcategory A2 projects do not necessarily require official NPS IACUC review; however, the NPS IACUC is recognized by the USDA APHIS AC as the final guarantor of AWAR compliance in the NPS. Thus, for this reason the NPS IACUC reserves the right to further review, require further alterations in, or overrule/reject the IACUC approval any Subcategory A2 project. To be classified as a Subcategory A2 project, the acknowledged PI/submitter for that project must provide to the NPS IACUC a copy of the approving IACUC's approval and a detailed Study Plan covering all aspects of the project, especially all procedures regarding animal handling.
- **§2.1 (a) (4) B.2.c: Subcategory A3.** Projects involving the use of vertebrate animals in NPS units that are judged by the NPS IACUC to cause harm, involve invasive procedures, or materially alter the behavior of animals under study, and which have not received prior review and approval from another properly registered IACUC are classified by the NPS IACUC as Subcategory A3 projects. Subcategory A3 projects must receive the full complement of the NPS IACUC review process for AWAR compliance.

§2.1 (a) (4) B.3: Amendment to an Ongoing Project. Projects approved by the NPS IACUC that are ongoing may be amended between renewal periods without completing a *de novo* resubmission; i.e. amendments to projects can be made provided the changes proposed are *significant*, but not to a degree that the seminal design of the project is permanently altered and thus must be resubmitted *de novo*. Significant changes to an ongoing protocol may constitute, but not be limited to: a change in project objectives; a change from nonsurvival to survival surgery (e.g. a change from project surgery protocol employing terminal procedures to one employing animal recovery post-surgery); a change in the degree of invasiveness of a procedure or discomfort to an animal; the addition of a new procedure or changing a procedure already in place; a change in the species and/or the number of animals being used; a change in project personnel; a change in anesthetic or analgesic protocol; a change in methods of euthanasia; and/or change in the duration, frequency, or number of procedures being performed on animals. The NPS IACUC reserves the right to discern/interpret what does and does not constitute a significant change to an ongoing project. Amendments to an ongoing NPS IACUC –approved project are submitted by the project PI via a completed NPS IACUC “Amendment to an Ongoing Project” form. Project amendments are then processed in the same fashion as the initial review; i.e. they are assessed for the content and/or character of significant changes within the context of AWAR compliance. Amendments may undergo review by either FCR or DMR. In the case of DMR, the original DMR for that project has first right of refusal to conduct the amendment review. The NPS IACUC neither conducts, nor accepts invitations to conduct, amendment reviews on Subcategory A2 projects.

§2.1 (a) (4) B.4: First and Second Year Reviews. NPS IACUC-approved projects carried-out over multiple years must be reviewed annually for the first two years. Such annual project reviews are submitted by the project PI via a completed NPS IACUC “Annual Project Review” form. Project annual reviews are then processed in the same fashion as the preliminary review;

i.e. they are assessed for their content and/or character of significant changes within the context of AWAR compliance. Annual reviews may undergo review by either FCR or DMR. In the case of DMR, the original DMR for that project has first right of refusal to conduct the annual review. The NPS IACUC neither conducts, nor accepts invitations to conduct, annual reviews on Subcategory A2 projects.

§2.1 (a) (4) B.5: Third Year Resubmissions. NPS IACUC-approved projects carried-out over multiple years must conduct a *de novo* resubmission prior to the start of their fourth year; e.g. *if a multi-year project was initially reviewed in January, 2011, then the first year renewal is due January, 2012; the second year renewal due January, 2013; and a de novo resubmission January, 2014 in order to continue past the end of the third year.* NPS IACUC-approved projects may undergo numerous periods of renewal and resubmission; e.g. projects may continue in this fashion as long as the project continually receives appropriate NPS IACUC review and approval.

§2.1 (a) (4) C: Approval, Rejection, and Appeal

For any given project, reviews by the NPS IACUC ultimately result in either approval or rejection. And during the review process, the Chair (or any other Committee member) may request additional materials from the PI in order to secure greater clarity regarding the project animal use protocol. Once a project receives final approval, official notification is sent to the PI in writing no later than twenty-four hours following the approving vote. Likewise, if a project is ultimately rejected, official notification is sent to the PI in writing, with an accompanying explanation, no later than twenty-four hours following the vote to reject. Section 2.31 (d) (4) of the AWAR states, “*The IACUC shall notify principal investigators and the research facility in writing of its decision to approve or withhold approval of those activities related to the care and use of animals, or of modifications required to secure IACUC approval. If the IACUC decides to withhold approval of an activity, it shall include in its written notification a statement of the reasons for its decision and give the principal investigator an opportunity to respond in person or in writing. The IACUC may reconsider its decision with documentation in Committee minutes, in light of the information provided by the principal investigator*”. Upon receipt of an NPS IACUC notification of project rejection (withhold of approval), a PI may appeal this decision in person or in writing, per the AWAR (*see above*). And the NPS IACUC may, if it so chooses, reverse its decision should it be swayed by the argument of the PI to do so; however, should the NPS IACUC uphold its decision to reject under such circumstances, no further appeal is possible.

§ 2.1 (a) (5): Research, Teaching, and Exhibition. The aforementioned, outlined protocols are applied equitably among the three mandated branches of NPS IACUC compliance: research, teaching, and exhibition. This is to say that the above outlined processes of project review are applied to all projects, whether they by nature involve research, teaching, or exhibition. Appropriate adjustments may be applied to submission, renewal, amendment, follow-up, and inspection forms accordingly when addressing research projects as opposed to teaching projects, etc. However, the core purpose behind each form remains consistent.

§2.1 (b): NPS Unit Permitting

National Park Service units issue permits –at their discretion- in order to officially support/give permission for certain activities within their respective boundaries. Such permits are often granted based upon a review of the proposed activities, weighed against the policies and regulations of the issuing NPS unit; i.e. whether or not the proposed activity is in compliance

with the mission and policies of the unit. Such permits are issued at the discretion of the individual NPS unit, and each NPS unit sets a unique, relevant set of permitting standards. Among the standards required by permit-issuing NPS units concerning research is the fulfillment of IACUC review. However, the NPS IACUC is restricted to project review regarding AWAR compliance only. What this means is that while a project may receive NPS IACUC review, and may indeed receive approval, such approval does not guarantee the issuance of a research permit by any NPS unit. NPS IACUC approval means a project is in compliance with the AWAR, and nothing else. Specifically, AWAR compliance does not necessarily equate to NPS compliance. An NPS IACUC-approved project may still run counter to the natural resource policies of a given NPS unit. Therefore, in a like situation, a permit may be withheld despite NPS IACUC approval.

§2.1 (c): Inspections

§2.1 (c) (1): Requirements. The NPS IACUC (the Committee) derives its mandate to inspect from the following: AWAR § 2.31 (c) (abbreviated): “*IACUC functions. With respect to activities involving animals, the IACUC, as an agent of the research facility shall: (1) Review the research facility’s program for humane care and use of animals, (2) Inspect all of the research facility’s animal facilities...except free-living wild animals in their natural habitat need not be included in such inspections,*”. The NPS IACUC is thus required by the AWAR to inspect the animal care and use program of the NPS; both on a regular basis through semi-annual reports and annual reports, and on as-needed basis through spot inspections of facilities. Regarding an NPS IACUC regulated program of inspection, section 2.31 (c) (2) of the AWAR states, “*Inspect, at least once every six months, all of the research facility’s animal facilities, including animal study areas, using title 9, chapter 1, subchapter A-Animal Welfare, as a basis for evaluation*”. The AWAR defines animal study areas in section 1.1 (Definition of Terms), “**Study area means any building room, area, enclosure, or other containment outside of a core facility or centrally designated or managed area in which animals are housed for more than 12 hours**”. The NPS IACUC is required by the AWAR to inspect animal study areas in the NPS, and must do so on a regular basis and/or as needed; either in response to a specific request or resulting from a concern, complaint, or similar “whistleblower” action.

§2.1 (c) (2): Forms. The NPS IACUC inspection form is another form in the NPS IACUC form catalogue. In a similar fashion to that of NPS IACUC project review, NPS animal facility inspections must have an organized, accompanying form in order to ensure a timely and thorough inspection process. Such an inspection form must be specific to the terms, needs, and regulations required of the inspection process. No final and/or permanent version can exist for the NPS IACUC inspection form, as flexibility and the ability to evolve with developing interpretations of the AWAR must be cornerstones of the NPS IACUC program. However, the NPS IACUC facility inspection form must be concise, relevant, plausible, and capable of facilitating a proper AWAR assessment in the most just, and expedient manner possible. And like the aforementioned project review forms, this form must be designed to expedite a thorough and proper AWAR assessment of any given NPS research facility.

§2.1 (c) (3): Protocol. Section 2.31 (c) (3) (abbreviated) of the AWAR states that the NPS IACUC must, “*Prepare reports of its evaluations conducted as required by paragraph (c) (1) and (2) of this section, and submit the reports to the Institutional Official of the research facility; Provided however, That the IACUC may determine the best means of conducting evaluations of the research facility’s programs and facilities; and Provided, further That no*

Committee member wishing to participate in any evaluation conducted under this subpart may be excluded. The IACUC may use subcommittees composed of at least two Committee members and may invite ad hoc consultants to assist in conducting the evaluations...” This section of the AWAE gives the NPS IACUC discretion to carry-out inspections and evaluations as it sees fit, as long as the requirements of the AWAR are met. This discretion is exercised in the creation of any and all necessary forms, inspection protocols, and communications dealing thereof. A single, set protocol designed to cover all inspections and inspection situations is impractical. Therefore, the NPS IACUC, in conducting inspections, will employ the guidance of AWAR subsections 2.31 (c) (1) and (2) as its guiding principles and format.

§2.1 (d): Training

Chiefly, it is the responsibility of the NPS IO to ensure that any and all relevant NPS personnel are adequately trained regarding the AWAR [*see AWAR § 2.32 (a), (b), and (c)*]. However, due to issues of practicality, the NPS IACUC assumes this duty by proxy, and carries-out this directive in three ways: through annual service-wide webinars, ongoing tutorials on the NPS IACUC website, and through the opportunity of presentations at any other event; e.g. conferences.

§2.1 (d) (1): Annual Service-Wide Webinars. At times to be determined annually by the NPS IACUC, service-wide webinars regarding the AWAR, the NPS IACUC, and/or any Animal Welfare-related topic must be presented. The purpose of these webinars is to train, educate, familiarize, and update the greater NPS community regarding the NPS IACUC purpose, functions, mandate, and organization. Such webinars may be organized and/or hosted by any member of the NPS IACUC.

§2.1 (d) (2): Website Training. The NPS IACUC will make available –on its website or by any other means upon request- training modules regarding the AWAR, the NPS IACUC, and any relevant information pertinent to individuals coordinating with the NPS IACUC; e.g. principal investigators, exhibitors, teachers/instructors, and or the NPS and public communities at-large. Unlike the periodic annual webinars, the information provided on the website tutorials will serve a dual purpose of fulfilling NPS IACUC protocol submitter requirements in addition to providing education and training; e.g. individuals making submissions to the NPS IACUC must complete the training modules prior to -and as part of- completion of the general submission form. The NPS IACUC training modules will be available on a continual basis, and may be updated or amended as needed.

§2.1 (d) (3): General Presentations. Members of the NPS IACUC will make every effort to attend, and participate in Animal Welfare conferences each year; e.g. the Public Responsibility in Medicine and Research (PRIM & R). Members of the NPS IACUC will also make every effort to attend and participate in NPS activities with an eye toward representing the Committee and its mandate. *It is strongly recommended that every member of the NPS IACUC attend the PRIM & R annual conference at least once during his or her three year term.*

§2.1 (e): Meetings

Sections 2.31 (c) (1) and (2) of the AWAR state (collectively) with regard to IACUC functions that an IACUC must, “*Review and Inspect at least once every six months, the research facility’s program for humane care and use of animals and animal facilities..*”. Thus the minimum required number of NPS IACUC meetings per the AWAR is once per annum;

however, the NPS IACUC must attempt to officially convene at least once per month; i.e. twelve times per year.

§2.1 (e) (1): Schedule. While the minimum number of meetings for the NPS IACUC is twelve per year, it is strongly suggested that official meetings –with a quorum- be held twice per month on the first and third Mondays of each (providing flexibility for holidays and the inability to attain a quorum during certain times of the year), in order to further facilitate NPS IACUC business and project review. The minimum meeting frequency of the NPS IACUC is once per month, with every attempt to meet twice per month or more.

§2.1 (e) (2): Agenda and Formatting. Per the AWAR, the organization and character of NPS IACUC meetings are left to the NPS IACUC to format outside of necessitating a quorum. Thus, the meeting format provided is a suggestion, and is subject to modification as needed:

- INTRODUCTION
 - o Quorum
 - o Attending
 - o Absent
- BUSINESS from the PREVIOUS MEETING
- NEW BUSINESS
- ACTION ITEMS
- CLOSING

The NPS IACUC Chair may also call meetings as needed to address urgent matters facing the Committee.

§2.1 (f): Reports

The NPS IACUC is primarily responsible for three main reports. Reports of lesser significance are not covered here, and are subject to the judgment and authority of the NPS IACUC as needed. The three main reports regarding the NPS IACUC are the Annual Report, the Semi-Annual Report, and any General Report of Non-Compliance.

§2.1 (f) (1): The NPS IACUC Annual Report. Section 2.36 (a) of the AWAR presents the character of the Annual Report (AR), and states (abbreviated), “*Each reporting facility shall submit an annual report to the AC Regional Director for the State where the facility is located on or before December 1 of each calendar year. The report shall be signed and certified by the CEO or Institutional Official, and shall cover the previous fiscal year.*” Section 2.36 (b) of the AWAR presents a more detailed list of items that must be covered in the AR. The NPS IACUC AR is compiled by the NPS IACUC Chair, and submitted to the NPS IO for review, editing, certification, signature, and final submission to the USDA APHIS AC. The NPS IACUC AR should be submitted to the NPS IO well in advance of the December 1 deadline; e.g. by November 1 of that year at the latest in order to provide the NPS IO sufficient time to adequately review and process the report. The NPS IACUC Chair should always keep in mind that the NPS IACUC AR is ultimately submitted to, and reviewed by, Congress.

§2.1 (f) (2): The NPS IACUC Semi-Annual Report. Sections 2.31 (c) (1) and (2) of the AWAR state (collectively) with regard to IACUC functions that an IACUC must, “*Review and Inspect at least once every six months, the research facility’s program for humane care and use of animals and animal facilities..*” This is the same section pertaining to meetings of the IACUC,

yet it also pertains to, and mandates, the NPS IACUC Semi-Annual Report (SAR). Like the AR, The SAR is compiled by the NPS IACUC Chair and submitted to the NPS IO for review, editing, and signature; however, unlike the AR, the SAR is neither submitted to the USDA APHIS AC, nor Congress. Instead, official, signed SARs are filed with the NPS IO, and remain there for a minimum of five years, if not in perpetuity. Specifics of the SAR are p outlined in the above referenced section of the AWAR, and need not be duplicated here.

§2.1 (f) (3): Reports of Non-Compliance. Section 2.31 (c) (3) of the AWAR states (abbreviated) in reference to reports of non-compliance, *“The reports must distinguish significant deficiencies from minor deficiencies...If program or facility deficiencies are noted, the reports must contain a reasonable and specific plan and schedule with dates for correcting each deficiency. Any failure to adhere to the plan and schedule that results in a significant deficiency remaining uncorrected shall be reported in writing within 15 business days by the IACUC, through the Institutional Official, to APHIS and any Federal agency funding that activity”*. Moreover, AWAR section 2.37 (b) establishes that the NPS IO has final authority regarding noncompliance deficiencies and subsequent *“corrective actions to be taken at the research facility”*. Issues of noncompliance will be dealt with in the following manner:

- 1.) A quorum of the NPS IACUC will meet to identify the main issue(s) of non-compliance, and make recommendations to the NPS IO regarding corrective actions.
- 2.) The NPS IO, upon receipt of the Committee’s recommendations can a.) Accept the Committee’s recommendations, b.) Accept the Committee’s recommendations with alterations as the NPS IO sees fit, or c.) Reject the Committee’s recommendations outright and c1.) Ask the Committee for new set of recommendations or c2.) Create a de novo set of corrective actions authored by the NPS IO all together.
- 3.) The NPS IO will inform –in writing- the principal investigator involved in the noncompliance issue of the corrective action to be taken. Included in this notification will be the offices of the Chief of Natural Resources and Superintendent of the NPS unit(s) involved.

Final corrective actions will include a timeline for redressment followed by follow-up review. On behalf of the NPS IO; if the NPS IACUC decides that the problem has not been adequately rectified in the specified time period, then a full report of noncompliance will be sent to the USDA APHIS AC by way of the NPS IO.

§2.2: NPS IACUC Communication Protocols

§2.2 (a): Overview

Concerning Federal Institutions, The AWAR recognizes three central entities coined with the responsibility of assessing and ensuring compliance. These are the IACUC, the IO, and the USDA APHIS AC unit. As set forth in the AWAR, these entities must exchange information directly with each other, and in a manner unimpeded by bureaucratic precondition or restraint. Examples of this include, but are not limited to, SARs, ARs, and non-compliance reports from the IACUC to the IO and the USDA APHIS AC. Such official communiqués must travel directly from their source to their intended recipient(s) without having to pass through established institutional channels. In this manner, communication between the NPS IACUC and the NPS IO

functions outside the chain of command employed by the NPS. Official communications between the NPS IACUC and primary investigators, consultants, and/or other individuals and groups also follow a similar format; i.e. they are direct, between the concerned parties. The lines of communication established by the AWAR are of a deliberate character, and are designed to reinforce –in the most expedient manner possible- the ever-constant pursuit of assessing and maintaining compliance. These lines of communication are recognized and employed by all agencies in compliance with the AWAR. *Refer to Appendix G for a Communication Chart.*

§2.2 (b): Communication between the NPS IACUC and the NPS IO

As previously stated, communications between the NPS IACUC and the NPS IO must be direct, and unimpeded by institutional precondition or restraint. However, due to the fact that the individual serving as the NPS IO primarily serves as the NPS Deputy Director, Operations, it is impractical for the NPS IACUC to expect unfettered access to the NPS IO. Such communication between the two offices is thus direct in character, but in application usually proceeds through the NPS IOA and/or the NPS IODA (*see sections §1.1 (f) (1), (2), and (3) for descriptions of duties regarding the NPS IO, NPS IOA, and the NPS IODA*). Reports including the SAR, AR, and/or reports of Non-compliance must travel directly between the NPS IACUC and the NPS IO (IOA and/or IODA), and no one other than these two offices can act, comment, edit, or influence in any way, these matters.

§2.2 (c): Communication between the NPS IACUC and the USDA APHIS AC

Communication between the NPS IACUC and the USDA APHIS AC is unfettered, and occurs as needed. And while no individual post is identified as a single point of contact between the NPS IACUC (or the NPS IO) and the USDA APHIS AC, there are specific instances where the NPS IO must be such; e.g. only the NPS IO can submit the AR, and the NPS IO must be involved in all instances of reported non-compliance. Communications between the NPS IACUC and the USDA APHIS AC will –when appropriate- follow established protocols as set forth in the AWAR.

§2.2 (d): Communication between the NPS IACUC and the Fourth Entities

In a similar fashion to communication between the NPS IACUC and the USDA APHIS AC, communication between the NPS IACUC and any fourth party (e.g. investigators, agencies, and/or universities) is unfettered and direct. The NPS IACUC must have open and free communication with these entities in order to fulfill its mandate of ensuring AWAR compliance in the NPS. Communications between the NPS IACUC and Fourth Entities will –when appropriate- follow established protocol as set for the in the AWAR.

SECTION THREE: RESOURCES & INTANGIBLES

§3.1: Continuing Education

§3.1 (a): Overview

Serving on the NPS IACUC requires familiarity with not only the AWA, the AWAR, and the IRAC, but with the most current, up-to-date techniques in animal capture, restraint, surgery, physiology, pharmacology, general biology, and trends in research to name only a bear few. And the mission of the NPS IACUC to refine, replace, and reduce animal suffering through AWAR compliance is much enhanced by the pursuit of continuing education by its members.

§3.1 (b): NPS IACUC Member Requirements

Members of the NPS IACUC pledge to serve for a minimum of three years. During this time, it is required that each member apply himself/herself to the best of their ability toward ensuring AWAR compliance in the NPS. This includes a good faith effort to remain current regarding the dynamic facets of animal welfare, and related applications.

§3.1 (c): NPS IACUC Member Recommendations

Relative to the above section, it is recommended that each member of the NPS IACUC - during his/her three year term- make every effort to attend as many conferences, professional society meetings, and/or any other gathering convened for the purpose of furthering the AWA, AWAR, IRAC, or animal welfare in general. Of particular note are the annual conference of Public Responsibility In Medicine and Research (PRIM & R) conference sponsored by the USDA APHIS AC and the National Institute of Health Office of Laboratory Animal Welfare (NIH OLAW) and any opportunity to attend an official IACUC 101 course (also sponsored by USDA APHIS AC and NIH OLAW).

§3.2: Collaboration

§3.2 (a): Overview

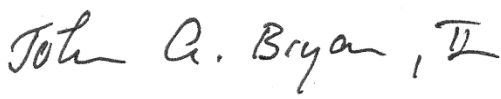
Collaboration between the NPS IACUC (by an individual member, group of members, or the full committee) and other entities is encouraged. And when financially feasible, every effort will be made to support such collaborations. Potential collaborative work of this kind could include, but not be limited to: publications regarding animal welfare, training, lectures, seminars, tutorials, and/or participation in national and international symposia regarding any and all aspects of animal welfare. Members of the NPS IACUC are encouraged to pursue collaborative work with non-NPS entities, especially those in academia, federal government, private industry, and the international forum [e.g. the OIE, WHO, and non-governmental organizations (NGOs)]. Such work only furthers the cause of promoting animal welfare.

§3.2 (b): Research and Publications

The AWAR has no preconditions regarding IACUC members and their ability to electively pursue research and publication aside from the following: AWAR §2.31 (d) (2) (abbreviated), *“No member may participate in the IACUC review or approval of an activity in which that member has a conflicting interest (e.g. is personally involved in the activity), except to provide information requested by the IACUC, nor may a member who has a conflicting interest contribute to the constitution of a quorum”*. If the actions of an NPS IACUC member fall within

these rules, he or she may pursue research and publication at their discretion, and may even submit such work to the NPS IACUC for review as long as they recuse themselves from review of that project. Additional recommendations and requirements may also be made in such circumstances by NPS policy.

This Standard Operating Protocol for the NPS IACUC has been submitted, reviewed, and approved by a full Committee of the NPS IACUC.

Chair: 

Date: October 10, 2012

SECTION FOUR: APPENDICES & REFERENCES

§4.1: Appendix A

The Nine Principals of the Interagency Research Animal Committee (IRAC)

PRINCIPLES FOR THE CARE AND USE OF ANIMALS USED IN TESTING, RESEARCH, AND TRAINING

The principles below were prepared by the **Interagency Research Animal Committee (IRAC)**. This committee, which was established in 1983, serves as a focal point for federal agencies' discussions of issues involving all animal species needed for biomedical research and testing. The committee's principal concerns are the conservation, use, care, and welfare of research animals. Its responsibilities include information exchange, program coordination, and contributions to policy development.

U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training

The development of knowledge necessary for the improvement of the health and well-being of humans as well as other animals requires *in vivo* experimentation with a wide variety of animal species. Whenever U.S. Government agencies develop requirements for testing, research, or training procedures involving the use of vertebrate animals, the following principles shall be considered; and whenever these agencies actually perform or sponsor such procedures, the responsible **Institutional Official** shall ensure that these principles are adhered to:

- I. The transportation, care, and use of animals should be in accordance with the Animal Welfare Act (7 U.S.C. 2131 et seq.) and other applicable Federal laws, guidelines, and policies.
- II. Procedures involving animals should be designed and performed with due consideration of their relevance to human or animal health, the advancement of knowledge, or the good of society.
- III. The animals selected for a procedure should be of an appropriate species and quality and the minimum number required to obtain valid results. Methods such as mathematical models, computer simulation, and *in vitro* biological systems should be considered.
- IV. Proper use of animals, including the avoidance or minimization of discomfort, distress, and pain when consistent with sound scientific practices, is imperative. Unless the contrary is established, investigators should consider that procedures that cause pain or distress in human beings may cause pain or distress in other animals.
- V. Procedures with animals that may cause more than momentary or slight pain or distress should be performed with appropriate sedation, analgesia, or anesthesia. Surgical or other painful procedures should not be performed on unanesthetized animals paralyzed by chemical agents.
- VI. Animals that would otherwise suffer severe or chronic pain or distress that cannot be relieved should be painlessly killed at the end of the procedure or, if appropriate, during the procedure.

- VII. The living conditions of animals should be appropriate for their species and contribute to their health and comfort. Normally, the housing, feeding, and care of all animals used for biomedical purposes must 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. In any case, veterinary care shall be provided as indicated.
- VIII. Investigators and other personnel shall be appropriately qualified and experienced for conducting procedures on living animals. Adequate arrangements shall be made for their in-service training, including the proper and humane care and use of laboratory animals.
- IX. Where exceptions are required in relation to the provisions of these Principles, the decision should not rest with the investigators directly concerned but should be made, with due regard to Principle II, by an appropriate review group such as an Institutional Animal Research Committee. Such exceptions should not be made solely for the purposes of teaching or demonstration.

The IRAC body is composed of representatives from the following federal agencies:

- U.S. Department of Agriculture
- U.S. Department of Defense
- U.S. Department of Energy
- U.S. Department of the Interior (*National Park Service*)
- U.S. Department of Health and Human Services
 - U.S. Department of State
 - U.S. Department of Transportation
 - U.S. Department of Veterans Affairs
- The Consumer Products Safety Commission
- The Environmental Protection Agency
- The National Aeronautics and Space Administration
 - The Smithsonian Institution
- The U.S. Agency for International Development
- The Centers for Disease Control and Prevention
 - The Food and Drug Administration
 - The National Institutes of Health
- The Office of International and Refugee Health

§4.2: Appendix B

The Enumerated Duties of the NPS Institutional Official (NPS IO)

1. Legally signs and commits the NPS to meet the requirements of the AWAR, (AWAR § 1.1)
2. Signs and submits the registration form and is responsible for notifying the USDA APHIS AC of any changes in the NPS registration, [AWAR §2.30 (a) through (c)].
3. Signs and submits the Annual Report to the USDA APHIS AC, [AWAR §2.36 (a)].
4. Receives Semi-Annual Reports, Inspection Reports, and Recommendations from the NPS IACUC, [AWAR §2.31 (c) (3) and (5)].
5. Consults with the NPS IACUC to determine if deficiencies are significant or minor, [AWAR §2.31 (c) (3)].
6. Forwards NPS IACUC reports of uncorrected significant deficiencies to the USDA APHIS AC and any federal agency funding that research, [AWAR §2.31 (c) (3)].
7. Receives notification of the NPS IACUC's decision to approve or withhold its approval of animal activities, [AWAR §2.31 (d) (4)]. *This will be accomplished primarily through the SAR reports, unless necessity dictates a more prompt response.*
8. Provides final decisions regarding corrective actions for issues of non-compliance; and receives consult from NPS IACUC regarding suspensions and corrective actions; and reports to regulatory and funding agencies [AWAR §2.31 (d) (7)].
9. May subject protocols that have been approved by the NPS IACUC to further review and approval, but may not approve an activity that has not been approved by the NPS IACUC [AWAR §2.31 (d) (8)].
10. In collaboration with the NPS IACUC, ensures that all personnel involved in animal care, treatment, and use are qualified to perform their duties and that training and instruction in specific areas are provided to those personnel, [AWAR §2.32 (a) and (c)].
11. In collaboration with the NPS IACUC, ensures that instruction and training are made available and that the qualifications of personnel are reviewed with sufficient frequency to fulfill the research facility's responsibilities, [AWAR §2.31 (b)].
12. Ensures that the NPS IACUC has an Attending Veterinarian (AV) who provides adequate veterinary care to its animals in compliance with the AWAR, [AWAR §2.33].

13. Ensures that any part-time AVs are employed under a formal written program of veterinary care, [AWAR §2.33 (a) (1)]. *Such part time AV positions are filled by wildlife veterinarians of the NPS Natural Resource Stewardship and Science Directorate; Biological Resource Management Division, Wildlife Health Branch.*
14. Ensures that the NPS maintains required records for the specified period of time; e.g. seven years minimum, [AWAR §2.35].
15. If applicable, the NPS IO will certify to the USDA APHIS AC that any outside facilities holding animals for the NPS are recognized animal sites under the NPS's research facility registration, [AWAR §2.38 (i) (3)]. *It is the responsibility of the NPS IACUC to locate, identify, and inspect such facilities within the NPS. Reports of inspections of such will be presented to the NPS IO with SAR reports or as circumstances dictate.*
16. Coordinates and finalizes NPS IACUC membership, [AWAR §2.31 (a)].

§4.3: Appendix C

The Enumerated Duties of the NPS IACUC Chair [AWAR §2.31 (c) (3); (d) (2); (d) (4); and §2.35 (a)]

1. Ensure that a quorum of the NPS IACUC is present.
2. Declare the loss of a quorum, resulting in the end of official business if a sufficient numbers of members depart.
3. Prepare or oversee the preparation of meeting minutes and reports and submit these documents to the NPS IO in accordance with AWAR policy,
4. Report to the NPS IO any projects that have been suspended by the NPS IACUC for noncompliance with the AWAR.
5. Establish a sound system of written communication for the NPS IACUC with investigators concerning the approval status of projects and the steps necessary to secure approval.
6. Establish a sound system of project review including NPS IACUC meeting schedules, agendas, format, and consultation with the USDA APHIS AC when needed.
7. Establish a sound system through which each NPS IACUC member can readily access any and all project information relevant to the review process.
8. Assist the NPS IO in coordinating membership to the NPS IACUC, and in any other duty requested by the NPS IO.
9. Keep abreast of new regulatory trends and interpretations and evaluate and champion policy and practice initiatives (e.g. new training and educational programs) to improve the NPS animal care and use program.
10. When called upon to do so, represent the NPS IACUC in any official capacity.
11. Maintain and upgrade the NPS IACUC Standard Operating Protocol as needed with the assistance of the NPS IACUC membership, office of the NPS IO, USDA APHIS AC, and appropriate consultation with outside entities.
12. Facilitate education and training regarding Animal Welfare for all NPS personnel.
13. Perform any and all duties related to the day-today function of the NPS IACUC and its mission to ensure AWAR compliance in the NPS.

§4.4: Appendix D

The Enumerated Duties of the NPS IACUC Attending Veterinarian (AV)
[AWAR §2.31 (d) (iv); (B); §2.31 (d) (vi); §2.31 (d) (vii); §2.31 (d) (ix); and §2.31 (d) (x) (B)]

1. Performs veterinary consultation to the NPS IACUC regarding the recognition and palliation of pain in animal subjects.
2. Directs the care and use of animals in the NPS.
3. Provides medical care to project animals in the NPS.
4. Performs and ensures any aseptic surgery and postoperative care to project animals in the NPS.
5. Provides oversight of multiple major survival surgery resulting from a veterinary condition in an animal that also had experimental surgery.
6. Provide professional veterinary medical consultation to the NPS IACUC on project reviews.
7. Delegate –as conditions may dictate, and as long as needed- his or her duties and responsibilities to another, accredited veterinarian.

§4.5: Appendix E

The Enumerated Duties of the NPS IACUC Unaffiliated Member At-Large (UMAL)

1. Serve the mission and purpose of the NPS IACUC to ensure AWAR compliance in the NPS.
2. Attend regular NPS IACUC meetings, participate in project reviews, and otherwise appropriately pursue greater training and knowledge regarding Animal Welfare.
3. Represent in person the “spirit” of the AWA and AWAR in serving the public interest toward maintaining the highest possible standards of animal care in the NPS. This duty to represent the general public on the NPS IACUC is unique to the UMAL.
4. Coordinate regularly and as needed with the NPS IACUC core membership (i.e. the Chair, AV, and regional membership) regarding Animal Welfare in their region.

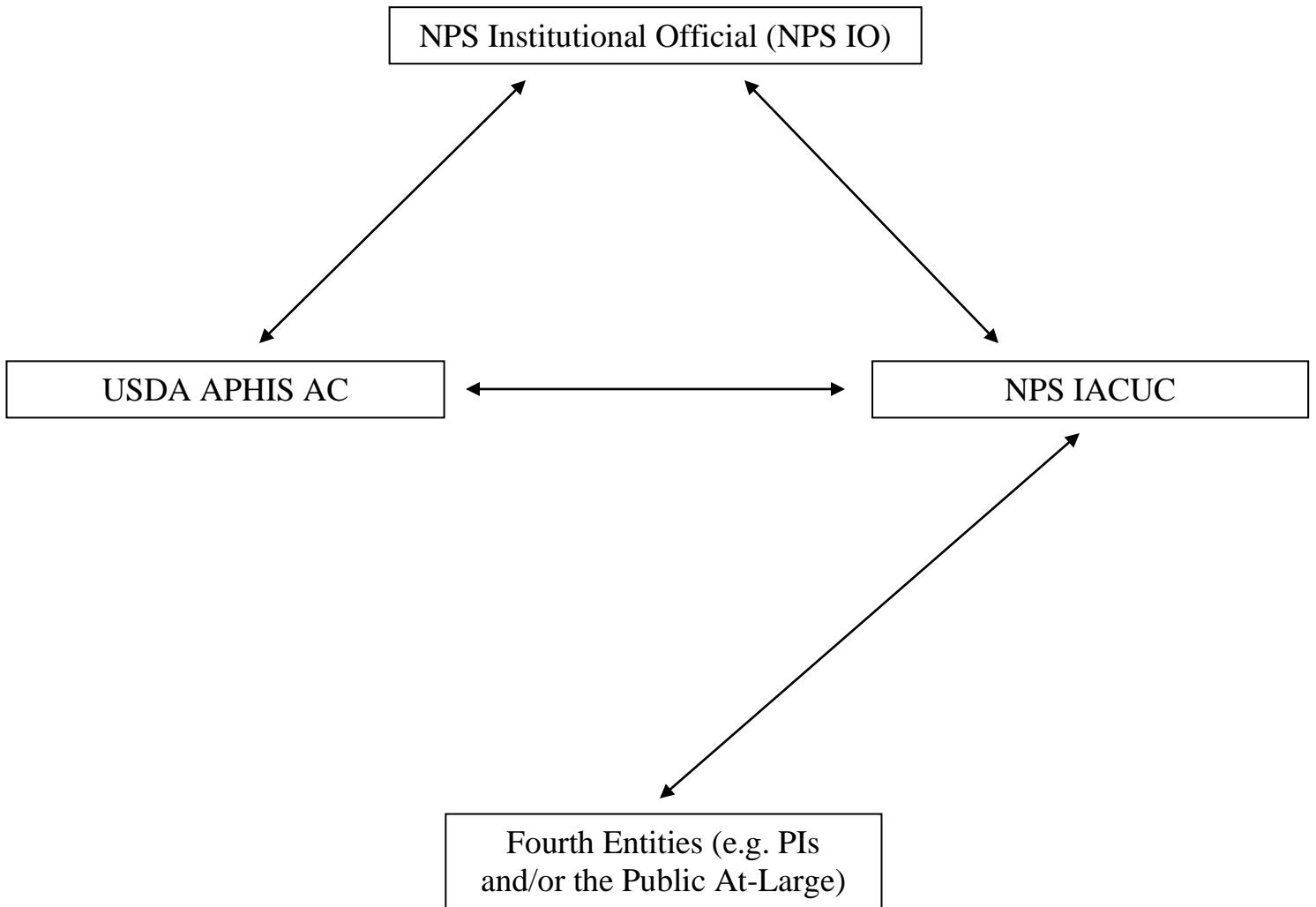
§4.6: Appendix F

The Enumerated Duties of the NPS IACUC Regional Members

5. Serve the mission and purpose of the NPS IACUC to ensure AWAR compliance in the NPS.
6. Attend regular NPS IACUC meetings, participate in project reviews, and otherwise appropriately pursue greater training and knowledge regarding Animal Welfare.
7. Serve as the primary contact(s) regarding Animal Welfare in their particular region.
8. Coordinate regularly and as needed with the NPS IACUC core membership (i.e. the Chair, AV, and UMAL) regarding Animal Welfare in their region.

§4.7: Appendix G

The NPS IACUC, NPS IO, USDA APHIS AC, and Fourth Entity Communication Chart



§4.8: References

The Animal Welfare Act (AWA) as of November 1, 2005. United States Code: Title 7 – Agriculture; Chapter 54 – Transportation, Sale, and Handling of Certain Animals. §2131 through 2159.

The Animal Welfare Act Regulations (AWAR) Revised as of January 1, 2005. United States Code of Federal Regulations: Title 9 – Animals and Animal Products; Chapter 1 – Animal Plant Health Inspection Service, Department of Agriculture; Subchapter A – Animal Welfare; Parts 1 through 4.

The Guide for the Care and Use of Laboratory Animals. The Institute of Laboratory Animal Resources, Commission on Life Sciences, National Research Council. National Academy Press, Washington D.C. 1996.

The IACUC Handbook; Second Edition. Jerald Silverman, Mark A. Suckow, and Treekant Murthy. CRC press. 2007.