



United States
Department of
Agriculture

Animal and
Plant Health
Inspection
Service

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NMFS, OPR1
1315 East West Highway
Silver Spring, MD 20910

May 1, 2007

Dear Tammy and Amy:

Thank you for the opportunity to comment on the scientific research permit applications involving Stellar sea lions and northern fur seals. The permit numbers involved are: 358-1888; 881-1745; 881-1893; 811-1890; 1034-1887; 782-1889; 715-1885; 434-1892; and 1049-1886. I apologize for any delay in submitting these comments.

The following comments apply to all permit applications, as they address general issues common to the collaborative study. After those comments, there will be some specific comments on several applications.

Branding

While there may be reasons to use hot branding for permanent identification, the activities in the multiple Stellar sea lion and northern fur seal applications do not warrant its use. The study design does not require and does not benefit from capture/release/recapture. All biochemical and body morphology do not require multi-year sampling of identified individuals. Any identification needed in one year to prevent resampling of the same animals can be served well by bleach or paint.

In addition, under the AWA, any time a potentially painful or distressful procedure is to be used, alternatives must be researched and final choices must be justified for the study. In this consideration of alternatives, reduction of numbers, refinement of technique, and replacement with other animals must be considered. If a study exists that requires hot branding (not considered humane), the length of time the branding takes, post procedure treatment and alleviation of pain, and other options must be considered. In the studies under review, there is no justification for using 4 digits, or for branding each digit alone. No consideration has been made for post procedure treatment with antibiotics or pain relief has been addressed. All facilities would be required to have an approved protocol from their IACUC that has shown consideration of alternatives and use of methods that would alleviate discomfort, stress, and long-term complications.

At a minimum, 3 digit branding is sufficient to mark more animals that needed for the studies (34X34X34 over 39,000 combinations, using only 0 and 1, not "o" and "l"). Additionally, devices should be used that load all three irons together so that only one application of the brand is used (20 sec as opposed to 2 minutes). Topical antibiotic-anesthetic crême should be used post procedure.

Branding should not be used unless it is the only means of identification possible. Since the protocols do not call for monitoring specific individuals as a key component, hot branding is not acceptable for these permits.





Veterinary procedures

The inclusion of statements about personnel being trained in a procedure does not exclude the PI or institution from following all tenets of the Veterinary Procedures Act in their States. Some of the specifics vary from state to state, but in general, only a licensed veterinarian can prescribe and administer drugs to animals, including anesthesia. California recently defined, by law, that "under direct supervision" of a veterinarian means that the veterinarian is right there during the procedure. All permit applicants must be sure that only qualified veterinarians perform activities as described under the practice acts, including drug administration, prescribing of drugs (dosages, methods, etc.), and surgical techniques, such as the described biopsies. A qualified veterinarian needs to be on site during all activities that involve veterinary procedures and drugs.

No consideration was given to proper recovery times for anesthesia. While an animal may be awake and mobile within 20 minutes of cessation of isoflurane, it is a recognized occurrence in veterinary medicine that the effects of anesthesia do not dissipate after 20 minutes. In practice, we have seen animals take up to 24-48 hours to recover from anesthesia, especially when the procedure of lengthy (over an hour).

In the event of accidental mortalities, one permit application said that maybe necropsies would be done. Under the AWA, all marine mammal deaths require a necropsy performed by or under the direct supervision of a qualified veterinarian. This condition would be applicable during research as well, as long as the animal was available. All applications that may result in accidental losses should address this issue.

While small surface skin biopsies may be acceptable without anesthesia under some conditions, proposals for blubber and muscle biopsies, some up to 2 1/2 inches deep, constitute painful and invasive procedures and must be done under anesthesia. If local anesthesia is to be used, dosages should be given, and well as documented protocols for determination of effectiveness, including the waiting period for full effect.

The amount of blood expected to be taken at sampling, while below 10% of blood volume, are significantly high. Given the state of current laboratory methods, it seems that samples can be much smaller, as most tests no longer require 5 ml of serum anymore, more like 0.1 ml. Remember refinement and reduction – this can be applied to sampling as well.

IACUC

All permit applications should include approved IACUC protocols for the proposed research. It is understood that NMMU is in the process of establishing IACUC procedures, but all other applications should have functioning IACUCs and should include approval of the protocols. As discussed above, all should address the potentially painful procedures and care of the animals.

Capture methods

All methods need to be reviewed to minimize stress and discomfort for the animals and alternatives need to be explored, decisions justified. No animal should be kept over 24 hours. Food and water issues must be addressed if held more than a few hours.

Body composition measures

Applicants identify that studies have already proven that certain methods are equivalent to the "gold standard" – deuterium(?) measures – for determining body composition. Therefore, it appears to be redundant and unnecessary for more than one method be used, increasing the handling and sedation/anesthesia. Only one method for determination of body composition should be used for each study. The intent of the studies is to monitor the animals, not compare methodologies. As an endangered species, these sea lions should be studied, not experimented on.

Specific applications:

**NMML:**

The application should include specifics, not generalities. Specific sites, animal numbers, etc., need to be identified. The general comments above apply to this application as well. Since there is no IACUC in place yet, detailed information is needed so that your office can adequately review. Justification of the studies should not be predicated on a prior study, but must be valid studies in their own right.

Tooth extraction (this can be applied to all applications as well) has not been justified, as there are no aspects of the study that require precise aging. The categories referenced are broad and the experienced and trained researchers should be able to tell approximate age without having to pull a tooth and the dangers the procedure entails (anesthesia, malocclusion, dental abscesses, pain).

Any decision on the use of anesthesia needs to be left to the veterinarian, not the PI, unless he/she is a qualified veterinarian.

ASLC:**Northern Fur seals:**

Discussion of threshold levels for mortality and stopping need to be addressed. It is unclear what that level is. Level may be same or different for level A and level B harassment activities. Express the results as real numbers, for example, the studies will be stopped if 1 level A animal dies, or if 3 level B animals die. These are not suggestions for the levels, but examples.

The institution needs to address alternatives to biopsy techniques proposed, and if muscle biopsies are needed. There is no justification presented for this sample. All prior comments apply to this application as well.

Use of sedation and anesthesia must be under the direct supervision of a qualified veterinarian. Valium is a controlled substance and can only be prescribed and dispensed for a specific patient by a veterinarian.

Captive breeding SSL:

The facility does not have room for additional Stellar sea lions, as at least one of the ODL pools identified is not large enough. There does not appear to be a valid reason to breed this endangered species in captivity, unless they are being bred for future release. As this process has not proven successful with marine mammals, use of these animals, already subject to a large number of experimental protocols, will not benefit the species or the animals themselves. In addition, issue of export and import of animals was not addressed. Any approval of this protocol is not permission for such movements. Those movements require other permits or approval. If the animals were impregnated, all other experimentation and sampling should be discontinued, as pregnancy will interfere (potentially) with other studies, and other manipulations would endanger the pregnancy. With such a small sample size, it is very doubtful that any significant studies could be performed/data analyzed. This project should not be approved. It appears to violate the ESA and does not benefit the animals.

For all of the permit applications, removal of branding and assurance of appropriate use of veterinarians in the protocols, could lead to acceptable protocols. All institutions and researchers where applicable must have approved protocols that mirror the applications before approval of the permits are given. The captive breeding permit is recommended to be denied. Any breeding of Stellar sea lions should be done only at facilities that have room and can maintain a breeding colony, without exposing the animals to research protocols.



Thank you again for the opportunity to comment on these proposals. Please contact this office if there are any further questions or concerns.

Sincerely,

A handwritten signature in cursive script that reads "Barbara Kohn".

Barbara Kohn
Senior Staff Veterinarian
Animal Care