DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

May 26, 2005

TO: Addressees

FROM: Deputy Director for Intramural Research, NIH

SUBJECT: Timely Assessment and Resolution of Animal Issues Involving Potential Pain and Distress

Research animals housed in NIH facilities must be monitored daily for potential pain and distress. A timely, appropriate response is required when observations by principal investigators, veterinarians, animal care technicians or others, raise concern about the existence of potential pain and distress. Emergency or acute conditions call for a veterinary response on the same day, although other issues, e.g., overcrowding, etc., may be appropriately handled within 24 hours. Sound judgement by those trained in the health and well-being of research animals is essential in making appropriate decisions regarding the need to notify the veterinarian. The veterinarian is responsible for discussing observations with the principal investigator to clarify the animal's condition and the need for intervention. To this end, clear, timely communications among all those involved in animal care and use are essential.

To formalize that process, the attached (Attachment 1) "Instructions for Animal Treatment and Care" form was incorporated as an attachment to the NIH Animal Study Proposal (ASP) (Attachment 1, Policy Manual 3040-2). The form serves to provide primary and alternate points of contact for both during and after work hours, specifies what restrictions, if any, may affect veterinary treatment of animals covered by each ASP, and any research criteria which may affect the method of euthanasia, if that decision is made by the veterinarian.

At Attachment 2 is a copy of the current ARAC Guideline "Communications Among Collaborating ICs and ACUCs". I continue to expect all NIH IRP Animal Care and Use program participants to read and comply with that document, which by virtue of this memorandum, is considered NIH IRP policy.

Please contact me, or the veterinary staff of the Office of Animal Care and Use at 301-496-5424 if additional information or clarifications are required.

Michael M. Gottesman, M.D.

Attachments

Addressees
IC Directors
Scientific Directors
IC ACUC Chairs
Animal Program Directors
IC Veterinarians
Animal Facility Managers
NIH IRP Principal Investigators
NIH IRP Animal Users

INSTRUCTIONS FOR EMERGENCY ANIMAL TREATMENT AND CARE
(Version 11/02)
(UPDATE ANNUALLY)

Principal Investigator: _____ Date form completed: _____
Protocol Number: _____
Office Phone: _____
Home Phone: _____

Protocol Title: _____

Use a separate form if ***care is different*** for each species

Species: _____ **Species**: _____
Species: _____ **Species**: _____

Animal Housing Location: Bldg _____
Use separate form if care differs by location
Bldg _____
Bldg _____

List of Procedures:
(surgery, tumor implant, catheter**)** _____

Primary Point of Contact (P.O.C.) in Case of Emergency: _____
Work Tel: _____ **Home Tel**: _____ **Beeper or Cell** #: _____

Alternate Point of Contact in Case of Emergency: _____
Work Tel: _____ **Home Tel**: _____ **Beeper or Cell** #: _____

Potential or Expected Complications: _____

Circumstances Requiring Contact: _____

Treatment (indicate appropriate response):

Treatment determined by **veterinarian**: ☐ Yes ☐ No

If **NO**, specify **restrictions** as follows: _____
Specific treatment as follows: _____

What **drugs** are **contraindicated**? _____

Criteria for **Euthanasia** (indicate appropriate response)

At Vet discretion if poor condition, severe pain or distress ☐ Yes ☐ No
If NO, specify treatments **or** restrictions: _____

Notify P.O.C. ☐ *Yes ☐ No
Requested **euthanasia agent and route of administration**: _____
Specific **criteria** for **euthanasia**: _____

If Euthanasia is performed or animals are found dead:

a. Contact P.O.C. ☐ Yes ☐ No
b. Refrigerate carcass ☐ Yes ☐ No
c. Dispose of carcass ☐ Yes ☐ No
d. Submit to VRP for necropsy ☐ Yes ☐ No

CAN number to use for submission: _____
Additional Comments: _____
Principal Investigator: _____
Signature **Date**

*** The veterinarian will take the appropriate action in an emergency if no response from the PI/POC is received within a half hour after an attempt at notification is made.**

Communications Among Collaborating ICs and ACUCs

Oversight and monitoring of ongoing animal activities to ensure the compliance with all regulations, policies and procedures remains a priority for all NIH Animal Care and Use Committees (ACUC). Of utmost importance in this monitoring process is appropriate and timely action to address issues that potentially or actually impact the health or well-being of animals.

Because animals in shared or central facilities are under the purview of a lead IC and its ACUC, systems to address program monitoring must be established between the lead and user ICs and their ACUCs. [Per PM 3040-2. Lead Institute - The user IC, which other user ICs authorize through an intraagency agreement, to manage a Shared Animal Facility(ies).]

This guideline outlines the processes for the monitoring of animal activities in shared and central facilities.

Although the principal responsibility for monitoring animal activities in shared or central facilities lies with the lead IC, user ACUCs are obliged to monitor the activities of their IC's investigators, within shared or central facilities. That function is typically delegated to the Animal Program Director (APD) of each IC. The APD, as an agent of their ACUC, takes an active role in monitoring to ensure that the animals' well-being is being provided for, and that actions taken by the Principal Investigators and associated IC investigative and technical staff are in compliance with procedures described in Animal Study Proposals (ASP)s associated with their studies. User IC APDs may further delegate that monitoring function to members of their staff. Monitoring will be performed through

- physical visits,
- professional interactions, and/or
- review of reports and records.

In addition, user ACUCs shall perform semiannual on-site assessments of their animals and associated animal activities in shared or central facilities, as noted in Policy Manual 3040-2, paragraph F.11.b.(1). User IC visits should be limited to

- assessment of IC animals,
- facility operations that directly affect those animals and
- procedure spaces used by IC investigators.

Such assessment visits will be coordinated with the facility management of the shared or central facility.

Minor operational issues that arise may be handled informally by the user IC's veterinary or management staff.

Issues that potentially or actually impact the health or well-being of animals require ACUC investigation and reporting as outlined by the August 22, 2001 memorandum from the Deputy Director for Intramural Research.

The following steps will be taken:

1. The ACUC Chairs of the lead and user ICs determine which ACUC will be the investigating ACUC.
    a. When an investigation in a shared or central facility results from actions or inactions of either the lead or a user IC and has, is, or will affect the health or well-being of animals belonging to the other user ICs, the lead IC ACUC will assume primary responsibility for the investigation and resolution of the issue.
    b. If a user IC’s actions or inactions leading to an investigation will not affect the health or well-being of animals belonging to any other IC, that user IC will assume primary responsibility for the investigation and resolution of the issue.
2. The Office of Animal Care and Use will be informed as soon as possible of any pending investigation and will participate as necessary.

3. The investigating ACUC, with the participation of member(s) from the directly involved ACUC(s), as appropriate, will conduct the investigation and prepare a report, describing
   a. the conclusions of the investigation
   b. recommendations made and adopted and
   c. corrective actions implemented.
4. The investigating ACUC's report, after discussion with other involved ACUCs, will be submitted to the involved ACUC(s) as well as to the Deputy Director for Intramural Research.

Approved ARAC, November 12, 1997
Revised - November 10, 1998
Revised - September 12, 2001
Revised - November 21, 2002
Reapproved - March 10, 2004