

threatening toxicity are required, and that we often must allow animals the opportunity to recover from severe toxic effects. Further, the exploratory nature of the work we do combined with the necessity to dose to overt toxicity sometimes leads to unpredicted reactions.

Therefore, there have been occasions, as reported in Column "E", when the decision to euthanize an animal was not reached quickly enough to prevent spontaneous death.

Oread recognizes such instances must be minimized, even if they cannot be eliminated entirely. Examples of on-going or completed activities designed to minimize the incidence of Column "E" events are:

1. Establishment of a "crash kit" of emergency medications and equipment made available to the vivarium staff so as to aggressively intervene when an animal becomes distressed.
2. Establishment of an objective list of clinical criteria which will prompt a consultation between the attending veterinarian and the study director to consider intervention alternatives.
3. Training of study directors to increase awareness of clinical indicators for intervention activity.

Additionally, in response to an USDA inspection, a decision was made by the IACUC that effective May 10, 1999 a new system would be implemented in which all high-dose and dose range-finding animals would be automatically categorized as Category "E". As described above, the regulatory bodies governing safety assessment studies require that dose levels are pushed to upper limits thus it is likely that these animals may experience some degree of pain and/or distress (e.g., lethargy, emesis).

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BY:.....

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UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO.
58-R-0015 58R0015

FORM APPROVED
OMB NO 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

2. HEADQUARTERS RESEARCH FACILITY (Name and Address, as registered with USDA, include Zip Code)

University of South Florida
12901 Bruce B. Downs Blvd.
MDC 20
Tampa, FL 33612
Status: Active

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets if necessary.)

FACILITY LOCATIONS (Sites)

See Attached

College of Public Health, USF, Site 002

J.A. Haley VA Hospital, Site 004

H. Lee Moffitt Cancer Ctr. & Res. Inst., Site 003 All Children's Hospital, Site 005

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use APHIS FORM 7023A)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain- relieving drugs.	D. Number of animals 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 were used	E. Number of animals 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. (An explanation of the procedures producing pain or distress in these animals and the reasons such drugs were not used must be attached to this report).	F. TOTAL NO. OF ANIMALS (Cols. C + D + E)
4. Dogs		0	34	0	34
5. Cats		1	78	0	79
6. Guinea Pigs					
7. Hamsters		11	0	0	11
8. Rabbits		36	108	38	182
9. Non-human Primates		46	0	0	46
10. Sheep		0	10	0	10
11. Pigs		11	74	0	85
12. Other Farm Animals					
GOATS		0	43	0	43
13. Other Animals					

ASSURANCE STATEMENTS

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility
- 2) Each principal investigator has considered alternatives to painful procedures
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL.
(Chief Executive Officer or Legally Responsible Institutional Official)

I certify that the above is true, correct, and complete (7 USC Section 2143)

(b)(6)(b)(7)(c)
SIGNATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL

NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL (Type or Print)

DATE SIGNED

10/27/99