

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO.

51-F-0016

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)

Warren Grant Magnuson Clinical Center
National Institutes of Health
10 Center Dr. Room 2C146
Bethesda, Maryland 20892

NOV 29 1999

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)

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 | 52 | 0 | 8 | 8 | 16 |
| 5. Cats | 0 | 0 | 0 | 0 | 0 |
| 6. Guinea Pigs | 0 | 2 | 0 | 0 | 2 |
| 7. Hamsters | 0 | 0 | 0 | 0 | 0 |
| 8. Rabbits | 0 | 0 | 8 | 0 | 8 |
| 9. Non-human Primates | 0 | 0 | 11 | 0 | 11 |
| 10. Sheep | | | | | |
| 11. Pigs | | | | | |
| 12. Other Farm Animals | | | | | |
| 13. Other Animals | | | | | |
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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)

SIGNATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL

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

DATE SIGNED

(b)(6) (b)(7)(C)

(b)(6) (b)(7)(C)

11/10/99

This form is intended as an aid to completing the Column E explanation. It is not an official form and its use is voluntary. Names, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation. A Column E explanation must be written so as to be understood by lay persons as well as scientists.

1. Registration Number: 51-F-0016
2. Number 8 of animals used in this study.
3. Species (common name) Dog of animals used in this study.
4. Explain the procedure producing pain and/or distress.

A canine model was developed to investigate the pathophysiology of and therapies of septic shock. This model is the only one which simulates the human cardiovascular abnormalities of sepsis, in which standard therapies are beneficial, and has been validated to predict outcome with novel therapies of sepsis. A live bacterial intraperitoneal infection was surgically introduced. This reliably produces sepsis and the animals become sick, weak, depressed, and 30-50% will succumb to infection. In an attempt to improve pain control, a trial blockade of afferent pain fibers originating from the visceral sympathetic nervous, a celiac plexus block, was performed. This study is listed in Column E because of the distress and discomfort associated with the systemic infection during the initial 48 hours and longer after the onset of infection.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see question 6 below)

Septic shock is the leading cause of death in medical intensive care units, and the incidence of septicemia has more than doubled in the last decade. Human septic shock has had a persistently high mortality rate despite conventional therapies; therefore, new therapies are desperately needed. Although narcotics and sedatives would potentially relieve suffering, these drugs also cause respiratory depression and worsen hypotension that could further compromise the animal's health and therefore are contraindicated for the treatment of septic shock. Furthermore, the use of narcotics and sedatives would effect survival and confound the analysis of results. Nevertheless, our protocol specifies that if at any time in the study the supervising veterinarian or principal investigator determines that an animal is enduring excessive pain and distress, we would euthanize the animal.

6. What, if any, federal regulations require this procedure? Cite the agency, the Code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

Agency NIH CFR N/A