

63R0005

## Optional Column E Explanation Form

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: 63 — R — 005
2. Number 49 of animals used in this study.
3. Species (common name) canine (dogs) of animals used in this study.
4. Explain the procedure producing pain and/or distress.

The dogs are in category E because they are used in a study evaluating the effects of sepsis on glucose metabolism. In critically ill septic patients, glucose metabolism is significantly altered and understanding the underlying physiology would facilitate the management of these patients. The dogs are surgically instrumented with indwelling catheters under anesthesia. Several weeks later, in a second survival surgery, the dogs receive an intraperitoneal fibrin clot containing a titrated amount of E.coli. Other dogs receive a sterile fibrin clot. Following clot administration a glucose metabolism study is performed on the dogs. The category E designation is due to the fact that analgesics are not administered to dogs during the thirty-six hours following septic clot administration. Dogs treated with the septic clot may become febrile and lethargic during the thirty -six hour period.

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)

This potential pain/distress is not treated with analgesics. The investigator is scientifically justified to the IACUC that the use of nonsteroidal anti-inflammatory analgesics and even opiod analgesics would modify the septic response. The investigator is very concerned about animal welfare and has titrated the dose of E.coli and sterile clot dogs based on clinical signs.

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): N/A

Agency \_\_\_\_\_ CFR \_\_\_\_\_

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO.

120595-F-0001

FORM APPROVED  
OMB NO. 0579-0036

EL

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

Commander, Tripler Army Medical Center  
Department of Clinical Investigation -  
ATTN: [REDACTED]  
Tripler AMC, HI 96859-5000

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

ANNUAL REPORT OF RESEARCH FACILITY  
(TYPE OR PRINT)

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)

Bldg. 147B/148, Animal Facility, TAMC

Bldg. 40, Animal Research Facility, TAMC

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					
5. Cats					
6. Guinea Pigs	18	26	10	13	49
7. Hamsters					
8. Rabbits					
9. Non-human Primates					
10. Sheep					
11. Pigs			16		16
12. Other Farm Animals					
Goats			15		15
13. Other Animals					
Ferrets			5		5

ASSURANCE STATEMENTS

- 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.
- Each principal investigator has considered alternatives to painful procedures.
- 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.
- 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.

RECEIVED  
OCT 22 1999  
SACRAMENTO, CA

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