UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. REGISTRATION NO.
51-F-003 0003

FORM APPROVED
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

443

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

Armed Forces Radiobiology Research Institute
8901 Wisconsin Ave.
Bldg. 42
Bethesda, MD 20889-5603

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		43		20	63
5. Cats					
6. Guinea Pigs		41	229	61	331
7. Hamsters					
8. Rabbits					
9. Non-human Primates		8	126		134
10. Sheep					
11. Pigs			17		17
12. Other Farm Animals					
13. Other Animals					
Ferret			22		22
Mouse		7,468	498	10,234	18,200
Rat		175	44		219

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 U.S.C. Section 2143)

SIGNATURE OF C.E.O. OR INSTITUTIONAL OFFICIAL	NAME & TITLE OF C.E.O. OR INSTITUTIONAL OFFICIAL *(Type or Print)*	DATE SIGNED
[redacted] (b)(6) (b)(7)(C)	[redacted] AFRRI (b)(6) (b)(7)(C)	24 Nov 99

APHIS FORM 7023
(AUG 91)

(Replaces VS FORM 18-23 (OCT 88), which is obsolete.)

KAEC

PART 1 - HEADQUARTERS

51F0003

Registration No. 51-F-003

Armed Forces Radiobiology Research Institute
8901 Wisconsin Ave. Bldg. 42
Bethesda, MD. 20889-5603

Attachment to APHIS Form 7023

Pain Category "E" Justification

Protocol **1**- 12 Canines

Nausea, retching and vomiting are associated with acute, but not chronic, gastrointestinal distress during the response to the cytoprotective agent or radiation. In order to determine whether we can alleviate it with said 5-HT3 receptor antagonist anti-emetics, we must determine the degree to which it appears under control conditions. Some analgesics have been shown to interfere with radiation-induced emesis but further may influence the immune system. The latter would confound future work in irradiated animals. Opioids and sedatives are typically anti-emetic and will thus interfere with the response we are studying or confound the anti-emetic properties of Kytril®. Likewise, these compounds can interfere with neutrophil function, which would also confound any future radiation studies. There may be some discomfort associated with the cardiovascular hypotension, if it occurs. However, since the hypotensive effects of Amifostine® are unclear and may be integrally linked with the nausea and vomiting, we also cannot relieve this symptom.

Protocol **2**- 8 Canines

Analgesics would interfere with the identification of clinical signs, hematological parameters, and survivability and therefore will not be administered. For example, analgesics my influence the immune system, which is one of the major targets of radiation.

Sedatives and opiates are also known to affect neutrophil functions. Since neutrophils are affected by irradiation, use of sedatives could introduce a possible confounding effect on neutrophil function, a marker in this study; and therefore, sedatives will not be used.

The effects of analgesics on prostaglandins are known. Iloprost and misoprostol are two prostaglandin analogues used as protective drugs. In fact, it has been shown in mice that the individual toxicity's of iloprost and misoprostol are annulled by mixing them together as will be done in this study.

Protocol **3**- 882 Mice

We are looking for neurological signs as an endpoint in this protocol. We cannot use drugs that will mimic or mask these signs or interfere with the immune response.

Opiates are reported to be associated with histamine release and they may cause CNS side effects that can confound the results of this particular study.

Glucorticoids lower seizure threshold and alter mood and behavior and at higher doses can alter the immune system and mask clinical signs of infection.

Non-Steroidal Anti-inflammatory Drugs (NSAIDs) may result in neurological toxicity as one of their adverse effects.

Protocol **4**- 17 Guinea Pigs

These experiments will set up a model which may prove useful for future studies that explore countermeasures and treatment on the effects of radiation on EEG and of the possible interactive effects of radiation, nerve agents, and sleep deprivation.

Protocol **5**- 3706 Mice