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OMB APPROVED
0579-0036
Exp.: 10/31/2018

This report is required by law (7 U.S.C. 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

Interagency Report Control No. 0180-DOA-AN

Fiscal Year 2017

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. REGISTRATION NUMBER
51-F-0006

2. HEADQUARTERS RESEARCH FACILITY *(Name, address, and telephone number as registered with USDA, include ZIP Code)*

US ARMY MED RESEARCH INST OF CHEMICAL DEFENSE
COMMANDER
3100 RICKETTS POINT ROAD
ABERDEEN PROV GRND, MD 21010

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)*

[redacted]

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 on these animals and the reasons such drugs were not used must be attached to this report.)*	F. TOTAL NUMBER OF ANIMALS **(Cols. C + D + E)**
4. Dogs	0	0	0	0	0
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	327	9	584	920
7. Hamsters	0	0	0	0	0
8. Rabbits	16	0	160	0	160
9. Non-human Primates	0	26	0	23	49
10. Sheep	0	0	0	0	0
11. Pigs	0	0	19	52	71
12. Other Farm Animals					
13. Other Animals	0	18	97	0	115

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 provisions 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 (C.E.O.) or Legally Responsible Institutional Official (I.O.))

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

[redacted]

DATE SIGNED
13-FEB-2018

APHIS FORM 7023
JUL 2013

OMB APPROVED
0579-0036

This report is required by law (7 U.S.C. 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150.

Interagency Report Control No. 0180-DOA-AN

Fiscal Year 2017

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

CONTINUATION SHEET FOR ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

1. REGISTRATION NUMBER
51-F-0006

2. HEADQUARTERS RESEARCH FACILITY *(Name, address, and telephone number as registered with USDA, include ZIP Code)*
US ARMY MED RESEARCH INST OF CHEMICAL DEFENSE
COMMANDER
3100 RICKETTS POINT ROAD
ABERDEEN PROV GRND, MD 21010

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY *(Attach additional sheets if necessary or use this form.)*

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 on these animals and the reasons such drugs were not used must be attached to this report.)*	F. TOTAL NUMBER OF ANIMALS **(Cols. C + D + E)**
FERRETS	0	18	97	0	115

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 provisions 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 (C.E.O.) or Legally Responsible Institutional Official (I.O.)*)

I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

[redacted]	[redacted]	DATE SIGNED
		13-FEB-2018

APHIS FORM 7023A
AUG 2013

Registration #51-F-0006

Protocol #1

1. Number of column "E" animals used in this study: 65

2. Species Used: Guinea Pigs

3. Painful procedure: Guinea pigs were exposed to various organophosphorus (OP) nerve agents in accordance with the details in the approved protocol.

4. Justification: The goal of this research is to evaluate the efficacy of novel bioscavenger enzymes in mitigating the consequences of nerve agent intoxication. Agent exposure potentially causes some pain and/or distress as a result of the intense physiological changes produced by these toxicants. Subjecting animals to levels of nerve agent exposure that reliably elicit these toxic effects is essential for the goals of this protocol. The use of anesthetics or analgesics would obscure the results, making it impossible to assess the efficacy of the candidate medical countermeasures.

5. No federal regulations mandate this procedure.

Registration #51-F-0006

Protocol #2

1. Number of column "E" animals used in this study: 327

2. Species Used: Guinea Pigs

3. Painful procedure: Animals are exposed to organophosphorus nerve agents and a vesicant. Agent exposure is thought to cause some pain and/or distress from the intense physiological changes produced by these toxicants. Vesicant exposure induces skin lesions and systemic toxicity which are considered to cause pain/distress.

4. Justification: Exposing animals to levels of chemical agents that reliably elicit toxic effects is essential for the goals of this protocol. Anesthetics and analgesics including non-steroidal anti-inflammatory drugs cannot be used in any experiments because of the possibility of interactions with the agents and/or the other drugs used in the protocol as pretreatment or post-challenge treatments.

5. No federal regulations mandate this procedure.

Registration #51-F-0006

Protocol #3

1. Number of column "E" animals used in this study: 83

2. Species Used: Guinea Pigs

3. Painful procedure: Animals are challenged with a nerve agent at a dose that elicits electrographic seizure activity.

4. Justification: There are no available computer models of nerve agent exposure or nerve agent-induced seizures and the response of brain tissue to collection of microdiasylates. Likewise, there are no in vitro models that simulate these processes as they are thought to occur in a live animal. Cell cultures or brain slices do not possess all the synaptic connections that occur in the intact animal, and these synaptic connections are essential for the measurement of real time in vivo acetylcholinesterase activity. Since the overall goal of the research is to determine real time acetylcholinesterase activity, information obtained using non-animal models may not accurately reflect activity in a whole animal.

5. No federal regulations mandate this procedure.

Registration #51-F-0006

Protocol #4

1. Number of column "E" animals used in this study: 105

2. Species Used: Guinea Pigs

3. Painful procedure: Guinea pigs in this project are injected with a lethal dose of neurotoxin, causing motor impairment and respiratory collapse.

4. Justification: The use of analgesics is not recommended for two reasons: First, analgesics, by reducing pain, may likely reduce clinical signs necessary to assess experimental effects of the agent and treatments in use. Second, the use of anesthesia may compromise respiratory function and therefore confound our ability to identify whether a specific countermeasure promotes survival. We have incorporated a humane endpoint score-sheet to help identify and implement clinical signs indicative of imminent death, thus enabling us to remove animals prior to death in certain cases.

5. No federal regulations mandate this procedure.

Registration #51-F-0006

Protocol #5

1. Number of column "E" animals used in this study: 4

2. Species Used: Guinea Pigs

3. Painful procedure: Guinea pigs were exposed to various OP nerve agents in accordance with the details in the approved protocol.

4. Justification: The goal of this protocol is to develop a point-of-care in-vitro diagnostic device to give indication of exposure to chemical warfare nerve agents. Subjecting animals to levels of nerve agent intoxication that reliably elicit the toxic responses is essential to the goals of this protocol. Agent exposure potentially causes some pain and/or distress as a result of the intense physiological changes produced by these toxicants. The use of anesthetics or analgesics would obscure the results, making it impossible to assess the performance of this medical device during development.

5. No federal regulations mandate this procedure.

Registration #51-F-0006

Protocol #6

1. Number of column "E" animals used in this study: 15

2. Species Used: Nonhuman Primates

3. Painful procedure: Agent Exposure

4. Justification: This protocol requires exposure to potentially lethal doses of chemical agents in unanesthetized nonhuman primates to monitor behavioral performance. Agent exposure is thought to cause some pain and/or distress because of the intense physiological changes produced by these toxicants. We cannot pre-treat the animals with any medication as this would compromise the results of the study in determining the dose of the chemical agent that leads to behavioral deficits.

5. No federal regulations mandate this procedure.

Registration #51-F-0006

Protocol #7

1. Number of column "E" animals used in this study: 8

2. Species Used: Nonhuman Primates

3. Painful procedure: Nerve Agent Exposure

4. Justification: All animals participated in an experiment which required exposure to potentially convulsive/lethal doses of nerve agents to monitor overt toxic responses. In the absence of protection, agent exposure is thought to cause some pain and/or distress due to the intense physiological changes produced by these toxicants. We cannot treat the animals with any other medications as this would compromise the results of the study in determining the protective efficacy of the bioscavengers alone. Additionally, the animals cannot be anesthetized as they need to exhibit the natural behavioral responses and in some cases perform behavioral tests to determine neurobehavioral protective efficacy and safety of the bioscavengers being tested.

5. No federal regulations mandate this procedure.

Registration #51-F-0006

Protocol #8

1. Number of column "E" animals used in this study: 41

2. Species Used: Swine

3. Painful procedure: Nerve agent exposure

4. Justification: This protocol requires exposure to otherwise convulsive or lethal doses of nerve agents in unanesthetized swine. Agent exposure is thought to cause some pain and/or distress because of the intense physiological changes produced by these toxicants. We cannot pretreat the animals with any medication as this would compromise the results of the study. The administration of anesthetics or analgesics to relieve pain or distress would lead to an erroneous evaluation of the toxicity of these agents and the efficacy of pretreatment, treatment, and decontamination procedures. Use of these anesthetics or analgesics would undermine the purpose of these experiments and may increase the number of animals needed to obtain statistical significance.

5. No federal regulations mandate this procedure.

Registration #51-F-0006

Protocol #9

1. Number of column "E" animals used in this study: 3

2. Species Used: Swine

3. Painful procedure: Nerve agent exposure

4. Justification: This protocol requires exposure to otherwise convulsive or lethal doses of nerve agents in unanesthetized swine. Agent exposure is thought to cause some pain and/or distress because of the intense physiological changes produced by these toxicants. We cannot pretreat the animals with any medication as this would compromise the results of the study. The administration of anesthetics or analgesics to relieve pain or distress would lead to an erroneous evaluation of the toxicity of these agents and the efficacy of pretreatment, treatment, and decontamination procedures. Use of these anesthetics or analgesics would undermine the purpose of these experiments and may increase the number of animals needed to obtain statistical significance.

5. No federal regulations mandate this procedure.

Registration #51-F-0006

Protocol #10

1. Number of column "E" animals used in this study: 8

2. Species Used: Swine

3. Painful procedure: Animals were administered a toxic chemical over multiple days.

4. Justification: There was no attempt to alleviate any pain associated with the development of liver fibrosis and/or cirrhosis. Analgesics may have confounded efficacy studies qualifying the effectiveness of the biomarker panel in evaluating the progression of liver disease. Some commonly used non-steroidal anti-inflammatory agents (NSAIDs) are known to cause liver damage and may exacerbate the toxicant-induced liver damage. Administration of anti-inflammatory or analgesic compounds was likely to cause changes in the host microbiome community, thus compromising experimental integrity by increasing variability. Therefore, animals which might have become moribund and/or showed unanticipated and/or undue pain and stress would have been euthanized.

5. No federal regulations mandate this procedure.
