DEPARTMENT OF THE ARMY
US ARMY MEDICAL RESEARCH INSTITUTE OF INFECTIOUS DISEASES
1425 PORTER STREET
FORT DETRICK, MARYLAND 21702-5011

November 08, 2017

REPLY TO
ATTENTION OF

Veterinary Medicine Division

27 NOV 2017

Elizabeth Goldentyer, D.V.M.
Director, Animal Welfare Operations
United States Department of Agriculture
Animal and Plant Health Inspection Services
Animal Care Eastern Region
920 Main Campus Drive, Suite 200
Raleigh, NC 27606-5213

Dear Dr. Goldentyer:

Enclosed is the United States Department of Agriculture 2017 Annual Report of Research Facilities for the United States Army Medical Research Institute of Infectious Diseases (USAMRIID), Registration Number 51-F-0021.

The annual report includes the National Institute of Health Poolesville Non-human Primate Facility, housing african greens, cynomolgus, rhesus, and marmosets for the USAMRIID. No research is conducted at Poolesville. This is considered a temporary arrangement and covered by an interagency Memorandum of Understanding.

The material enclosed has been reviewed and there is no objection to its release under Freedom of Information Act. All materials included in the report may be released to the public.

An updated list of key personnel is provided:

Commander: Colonel Gary A. Wheller
Institutional Official: Colonel Brian J. Gentile (Deputy Commander)
Attending Veterinarian: Colonel David E. Bentzel
IACUC Co-Chairs: Lieutenant Colonel Norman E. Kreiselmeier and Ms. Brenda O'Quinn

Please refer questions to the USAMRIID Attending Veterinarian, Colonel David E. Bentzel at 301-619-4717.

Sincerely,

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

Brian J. Gentile
Colonel, Veterinary Corps
Deputy Commander

According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0579-0036. The time required to complete this information collection is estimated to average 2 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

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

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

REGISTRATION NUMBER: 51-F-0021

Customer Number: 728

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

US Army Medical Research Institute of Infectious Disease
Veterinary Medicine Division
(b) (6), (b) (7)(C)

Telephone: (b) (6),

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 Listing*

US Army Medical Research Institute of Infectious Diseases, Fort Detrick, MD

National Institutes of Health (NIH), Animal Center, Poolesville, MD

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	2	0	0	0	0
6. Guinea Pigs	163	252	250	454	956
7. Hamsters	0	203	102	256	561
8. Rabbits	0	33	47	0	80
9. Non-human Primates	143	104	284	190	578
10. Sheep	0	0	0	0	0
11. Pigs	0	0	0	0	0
12. Other Farm Animals					
Goats	0	17	0	0	17
13. Other Animals					
Alpaca	0	2	0	0	2
Ferret	0	0	4	18	22

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).

SIGNATURE	NAME AND TITLE OF C.E.O. OR I.O. *(Type or Print)*	DATE SIGNED
(b) (6), (b) (7)(C)	Brian J. Gentile, Colonel, Institutional Official	08 Nov 17

AP
JUL 2013

27 NOV 2017

NPI/9/18

Optional Column E Explanation Form

27 NOV 2017

1. **Registration Number:** 51-F-021 / 728

2. **Number** 454 **of animals used in this study.**

3. **Species (common name)** Guinea Pigs **of animals used in this study.**

4. **Explain the procedure producing pain and/or distress.**

   Guinea pigs used in research at the United States Army Medical Research Institute of Infectious Diseases and reported in Column E experienced pain and/or distress due to one of the following circumstances:

   a. Use on a pathogenesis study in which they were infected by parenteral injection or aerosol exposure to a CDC Select Agent or other high hazard agent (bacterial or viral infectious agents) and allowed to develop the disease.
   b. Use on a vaccine study in which they were vaccinated against a CDC Select Agent or other high hazard agent (bacterial or viral infectious agents or biological toxins) and subsequently exposed by parenteral injection or aerosol exposure to the infectious agent or toxin. Animals that were used in control groups experienced pain and/or distress when they developed the disease as did any animals in which the vaccine was not completely efficacious in preventing the infection or intoxication.
   c. Use on a therapeutic study in which animals were treated with a drug either before or after exposure to a CDC Select agent or other high hazard agent (bacterial or viral infectious agents) by parenteral injection or aerosol exposure. Animals that were used in control groups experienced pain and/or distress when they developed the disease as did any animals in which the drug was not completely efficacious in preventing or treating the 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)**

The retardation or relief of clinical signs with pain relieving or anesthetic drugs result in inaccurate experimental data because these drugs interfere with certain clinical and immunological responses to biological agents by the test animal, and subsequent analysis of those responses. All studies that result in unalleviated pain or distress to experimental animals require scientific justification, in writing, explaining in detail, why the use of pain relieving drugs is not appropriate and how it would interfere with the scientific goals of the study. Each of these protocols is evaluated on a case by case basis by the IACUC.

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 N/A **CFR** N/A

Optional Column E Explanation Form

27 NOV 2017

1. **Registration Number:** 51-F-021 / 728

2. **Number** 256 **of animals used in this study.**

3. **Species (common name)** Hamsters **of animals used in this study.**

4. **Explain the procedure producing pain and/or distress.**

   Hamsters used in research at the United States Army Medical Research Institute of Infectious Diseases and reported in Column E experienced pain and/or distress due to one of the following circumstances:

   a. Use on a pathogenesis study in which they were infected by parenteral injection or aerosol exposure to a CDC Select Agent or other high hazard agent (bacterial or viral infectious agents) and allowed to develop the disease.
   b. Use on a vaccine study in which they were vaccinated against a CDC Select Agent or other high hazard agent (bacterial or viral infectious agents) and subsequently exposed by parenteral injection or aerosol exposure to the infectious agent. Animals that were used in control groups experienced pain and/or distress when they developed the disease as did any animals in which the vaccine was not completely efficacious in preventing the infection.
   c. Use on a therapeutic study in which animals were treated with a drug either before or after exposure to a CDC Select agent or other high hazard agent (bacterial or viral infectious agents) by parenteral injection or aerosol exposure. Animals that were used in control groups experienced pain and/or distress when they developed the disease as did any animals in which the drug was not completely efficacious in preventing or treating the 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)**

The retardation or relief of clinical signs with pain relieving or anesthetic drugs result in inaccurate experimental data because these drugs interfere with certain clinical and immunological responses to biological agents by the test animal, and subsequent analysis of those responses. All studies that result in unalleviated pain or distress to experimental animals require scientific justification, in writing, explaining in detail, why the use of pain relieving drugs is not appropriate and how it would interfere with the scientific goals of the study. Each of these protocols is evaluated on a case by case basis by the IACUC.

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 N/A **CFR** N/A

Optional Column E Explanation Form

1. **Registration Number:** 51-F-021 / 728 27 NOV 2017

2. **Number** 190 **of animals used in this study.**

1. **Species (common name)** Non-human Primates **of animals used in this study.**

2. **Explain the procedure producing pain and/or distress.**

Nonhuman primates used in research at the United States Army Medical Research Institute of Infectious Diseases and reported in Column E experienced pain and/or distress due to one of the following circumstances:

a. Use on a pathogenesis study in which they were infected by parenteral injection or aerosol exposure to a CDC Select Agent or other high hazard agent (bacterial or viral infectious agents) and allowed to develop the disease.
b. Use on a vaccine study in which they were vaccinated against a CDC Select Agent or other high hazard agent (bacterial or viral infectious agents or biological toxins) and subsequently exposed by parenteral injection or aerosol exposure to the infectious agent or toxin. Animals that were used in control groups experienced pain and/or distress when they developed the disease as did any animals in which the vaccine was not completely efficacious in preventing the infection or intoxication.
c. Use on a therapeutic study in which animals were treated with a drug either before or after exposure to a CDC Select agent or other high hazard agent (bacterial or viral infectious agents) by parenteral injection or aerosol exposure. Animals that were used in control groups experienced pain and/or distress when they developed the disease as did any animals in which the drug was not completely efficacious in preventing or treating the 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)

The retardation or relief of clinical signs with pain relieving or anesthetic drugs result in inaccurate experimental data because these drugs interfere with certain clinical and immunological responses to biological agents by the test animal, and subsequent analysis of those responses. All studies that result in unalleviated pain or distress to experimental animals require scientific justification, in writing, explaining in detail, why the use of pain relieving drugs is not appropriate and how it would interfere with the scientific goals of the study. Each of these protocols is evaluated on a case by case basis by the IACUC.

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 N/A **CFR** N/A

Optional Column E Explanation Form

1. **Registration Number:** 51-F-021 / 728 — 27 NOV 2017

2. **Number** 18 **of animals used in this study.**

5. **Species (common name)** Ferrets **of animals used in this study.**

6. **Explain the procedure producing pain and/or distress.**

Rabbits used in research at the United States Army Medical Research Institute of Infectious Diseases and reported in Column E experienced pain and/or distress due to one of the following circumstances:

d. Use on a pathogenesis study in which they were infected by parenteral injection or aerosol exposure to a CDC Select Agent or other high hazard agent (bacterial or viral infectious agents) and allowed to develop the disease.
e. Use on a vaccine study in which they were vaccinated against a CDC Select Agent or other high hazard agent (bacterial or viral infectious agents or biological toxins) Use and subsequently exposed by parenteral injection or aerosol exposure to the infectious agent or toxin. Animals that were used in control groups experienced pain and/or distress when they developed the disease as did any animals in which the vaccine was not completely efficacious in preventing the infection or intoxication.
f. Use on a therapeutic study in which animals were treated with a drug either before or after exposure to a CDC Select agent or other high hazard agent (bacterial or viral infectious agents) by parenteral injection or aerosol exposure. Animals that were used in control groups experienced pain and/or distress when they developed the disease as did any animals in which the drug was not completely efficacious in preventing or treating the 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)

The retardation or relief of clinical signs with pain relieving or anesthetic drugs result in inaccurate experimental data because these drugs interfere with certain clinical and immunological responses to biological agents by the test animal, and subsequent analysis of those responses. All studies that result in unalleviated pain or distress to experimental animals require scientific justification, in writing, explaining in detail, why the use of pain relieving drugs is not appropriate and how it would interfere with the scientific goals of the study. Each of these protocols is evaluated on a case by case basis by the IACUC.

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 N/A **CFR** N/A

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: 2018

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

REGISTRATION NUMBER: 51-F-0021

Customer Number: 723

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

US Army Medical Research Institute of Infectious Diseases
Veterinary Medicine Division
(b) (6), (b) (7)(C)

Telephone: (b) (6),

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 Listing*

National Institute of Health (NIH) Animal Center, Poolesville, MD

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	2	0	0	0	0
6. Guinea Pigs	213	541	296	592	1429
7. Hamsters	0	9	374	234	617
8. Rabbits	0	40	16	4	60
9. Non-human Primates	256	103	98	65	266
10. Sheep	0	0	0	0	0
11. Pigs	0	0	0	0	0
12. Other Farm Animals					
13. Other Animals					
Alpacas	0	2	0	0	0
Ferrets	0	2	0	0	0

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).

SIGNATURE OF C.E.O. OR I.O.	NAME AND TITLE OF C.E.O. OR I.O. *(Type or Print)*	DATE SIGNED
(b) (6), (b) (7)(C)	BRIAN J. GENTILE, Colonel, Institutional Official	05 NOV 18

APHIS FORM 7023
JUL 2013

29 NOV 2018

Optional Column E Explanation Form

1. **Registration Number:** 51-F-021 / 728

2. **Number** 592 **of animals used in this study.**

3. **Species (common name)** Guinea Pigs **of animals used in this study.**

4. **Explain the procedure producing pain and/or distress.**

   Guinea pigs used in research at the United States Army Medical Research Institute of Infectious Diseases and reported in Column E experienced pain and/or distress due to one of the following circumstances:

   a. Use on a pathogenesis study in which they were infected by parenteral injection or aerosol exposure to a CDC Select Agent or other high hazard agent (bacterial or viral infectious agents) and allowed to develop the disease.
   b. Use on a vaccine study in which they were vaccinated against a CDC Select Agent or other high hazard agent (bacterial or viral infectious agents or biological toxins) and subsequently exposed by parenteral injection or aerosol exposure to the infectious agent or toxin. Animals that were used in control groups experienced pain and/or distress when they developed the disease as did any animals in which the vaccine was not completely efficacious in preventing the infection or intoxication.
   c. Use on a therapeutic study in which animals were treated with a drug either before or after exposure to a CDC Select agent or other high hazard agent (bacterial or viral infectious agents) by parenteral injection or aerosol exposure. Animals that were used in control groups experienced pain and/or distress when they developed the disease as did any animals in which the drug was not completely efficacious in preventing or treating the 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)**

The retardation or relief of clinical signs with pain relieving or anesthetic drugs result in inaccurate experimental data because these drugs interfere with certain clinical and immunological responses to biological agents by the test animal, and subsequent analysis of those responses. All studies that result in unalleviated pain or distress to experimental animals require scientific justification, in writing, explaining in detail, why the use of pain relieving drugs is not appropriate and how it would interfere with the scientific goals of the study. Each of these protocols is evaluated on a case by case basis by the IACUC.

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 N/A **CFR** N/A

Optional Column E Explanation Form

1. **Registration Number:** 51-F-021 / 728

2. **Number** 234 **of animals used in this study.**

3. **Species (common name)** Hamsters **of animals used in this study.**

4. **Explain the procedure producing pain and/or distress.**

   Hamsters used in research at the United States Army Medical Research Institute of Infectious Diseases and reported in Column E experienced pain and/or distress due to one of the following circumstances:

   a. Use on a pathogenesis study in which they were infected by parenteral injection or aerosol exposure to a CDC Select Agent or other high hazard agent (bacterial or viral infectious agents) and allowed to develop the disease.
   b. Use on a vaccine study in which they were vaccinated against a CDC Select Agent or other high hazard agent (bacterial or viral infectious agents) and subsequently exposed by parenteral injection or aerosol exposure to the infectious agent. Animals that were used in control groups experienced pain and/or distress when they developed the disease as did any animals in which the vaccine was not completely efficacious in preventing the infection.
   c. Use on a therapeutic study in which animals were treated with a drug either before or after exposure to a CDC Select agent or other high hazard agent (bacterial or viral infectious agents) by parenteral injection or aerosol exposure. Animals that were used in control groups experienced pain and/or distress when they developed the disease as did any animals in which the drug was not completely efficacious in preventing or treating the 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)**

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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 N/A **CFR** N/A

29 NOV 2018

Optional Column E Explanation Form

1. **Registration Number:** 51-F-021 / 728

2. **Number** 4 **of animals used in this study.**

3. **Species (common name)** Rabbits **of animals used in this study.**

4. **Explain the procedure producing pain and/or distress.**

   Rabbits used in research at the United States Army Medical Research Institute of Infectious Diseases and reported in Column E experienced pain and/or distress due to one of the following circumstances:

   a. Use on a pathogenesis study in which they were infected by parenteral injection or aerosol exposure to a CDC Select Agent or other high hazard agent (bacterial or viral infectious agents) and allowed to develop the disease.
   b. Use on a vaccine study in which they were vaccinated against a CDC Select Agent or other high hazard agent (bacterial or viral infectious agents or biological toxins) Use and subsequently exposed by parenteral injection or aerosol exposure to the infectious agent or toxin. Animals that were used in control groups experienced pain and/or distress when they developed the disease as did any animals in which the vaccine was not completely efficacious in preventing the infection or intoxication.
   c. Use on a therapeutic study in which animals were treated with a drug either before or after exposure to a CDC Select agent or other high hazard agent (bacterial or viral infectious agents) by parenteral injection or aerosol exposure. Animals that were used in control groups experienced pain and/or distress when they developed the disease as did any animals in which the drug was not completely efficacious in preventing or treating the 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)**

The retardation or relief of clinical signs with pain relieving or anesthetic drugs result in inaccurate experimental data because these drugs interfere with certain clinical and immunological responses to biological agents by the test animal, and subsequent analysis of those responses. All studies that result in unalleviated pain or distress to experimental animals require scientific justification, in writing, explaining in detail, why the use of pain relieving drugs is not appropriate and how it would interfere with the scientific goals of the study. Each of these protocols is evaluated on a case by case basis by the IACUC.

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 N/A **CFR** N/A

Optional Column E Explanation Form

1. **Registration Number:** 51-F-021 / 728

2. **Number** 65 **of animals used in this study.**

1. **Species (common name) Non-human Primates of animals used in this study.**

2. **Explain the procedure producing pain and/or distress.**

Nonhuman primates used in research at the United States Army Medical Research Institute of Infectious Diseases and reported in Column E experienced pain and/or distress due to one of the following circumstances:

a. Use on a pathogenesis study in which they were infected by parenteral injection or aerosol exposure to a CDC Select Agent or other high hazard agent (bacterial or viral infectious agents) and allowed to develop the disease.
b. Use on a vaccine study in which they were vaccinated against a CDC Select Agent or other high hazard agent (bacterial or viral infectious agents or biological toxins) and subsequently exposed by parenteral injection or aerosol exposure to the infectious agent or toxin. Animals that were used in control groups experienced pain and/or distress when they developed the disease as did any animals in which the vaccine was not completely efficacious in preventing the infection or intoxication.
c. Use on a therapeutic study in which animals were treated with a drug either before or after exposure to a CDC Select agent or other high hazard agent (bacterial or viral infectious agents) by parenteral injection or aerosol exposure. Animals that were used in control groups experienced pain and/or distress when they developed the disease as did any animals in which the drug was not completely efficacious in preventing or treating the 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)

The retardation or relief of clinical signs with pain relieving or anesthetic drugs result in inaccurate experimental data because these drugs interfere with certain clinical and immunological responses to biological agents by the test animal, and subsequent analysis of those responses. All studies that result in unalleviated pain or distress to experimental animals require scientific justification, in writing, explaining in detail, why the use of pain relieving drugs is not appropriate and how it would interfere with the scientific goals of the study. Each of these protocols is evaluated on a case by case basis by the IACUC.

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 N/A **CFR** N/A