This report is required by law (7 USC 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.

See reverse side for additional information.

Interagency Report Control No. 0180-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NO. 10-F-0002 CUSTOMER NO. 439

FORM APPROVED OMB NO. 0579-0036

2. HEADQUARTERS RESEARCH FACILITY *(Name and Address, as registered with USDA, Include Zip Code)*
WALTER REED ARMY INSTITUTE OF RESEARCH
FREDERICK, MD

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)*

(b)(2)High, (b)(7)f

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		1	214	164	379
7. Hamsters			99		99
8. Rabbits		12	2		14
9. Non-Human Primates	74	177	68	4	249
10. Sheep			8		8
11. Pigs		1	609		610
12. Other Farm Animals					
13. Other Animals					
Ferrets			18	2	20

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 the 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)

(b)(6), (b)(7)c

DATE SIGNED 11/25/2008

ART 1 - HEADQUARTERS

(AUG 91)

Nf

APHIS Form 7023 Column E Explanation

This form is intended as an aid to completing the APHIS Form 7023 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.

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1. Registration Number: 10-F-0002

2/3. Species (common name) & Number of animals used in this study:

Guinea Pigs (164)

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

Protocol A:

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 Item 6 below)

Protocol A: The study of immune response to and protective efficacy of vaccine candidates directed against Shigella requires an accurate evaluation of the immune response raised by the administration of these vaccines. The use of analgesics, particularly opiates or narcotics, result in immunosuppression, which would invalidate the results of experiments testing immune responses as well as increasing the severity of the possible eye infection.

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: Protocol A: None CFR:

APHIS Form 7023 Column E Explanation

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1. Registration Number: 10-F-0002

2/3. Species (common name) & Number of animals used in this study:

Ferrets (2)

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

Ferrets will receive vaccine or control material then challenged with Campylobacter bacteria to see if the animals develop adequate immunity to resist the infection. Ferrets may experience the discomfort of diarrhea and possible, but unlikely dehydration.

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 Item 6 below)

Approximately 10% of the animals are placed in pain category E. These include animals that may have >2+ Campylobacter-associated diarrhea. These animals cannot be treated with analgesics or antibiotics, because the results obtained will be confounded. In addition, the recovery or lack of illness of immunized animals cannot be attributed to the efficacy of the vaccine. Analgesics are contraindicated since these agents would change the course of the disease and alter physiologic/pathologic endpoints. Therefore, no such pharmacological agents will be used due to the risk of interference with the outcome of the disease.

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: None CFR:

APHIS Form 7023 Column E Explanation

This form is intended as an aid to completing the APHIS Form 7023 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.

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1. Registration Number: 10-F-0002

2/3. Species (common name) & Number of animals used in this study:

Non-Human Primates (4)

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

Protocol A: Number of animals used in this study: 2

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 Item 6 below)

Protocol A: Because the measurement of the host-pathogen interaction is dependent upon a lethal model, it is important that the disease process not be interfered with. Because the illness is primarily mediated by a cellular immune response and the organisms are intracellular, analgesics will not be used post challenge. This is because narcotic analgesics cause histamine release. There is evidence for histamine involvement involved in bacterial infections. One aim of the study is to identify markers predictive of the severity of illness and also to identify rational therapeutic targets at each stage of illness using genetic and proteomic markers. We cannot afford to complicate this picture by using analgesics.

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: Protocol A: None CFR: