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
42-G-0001

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

National Animal Disease Center
P.O. Box 70

AMES, IA 50010

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	2	0	2	4
7. Hamsters	0	12	0	22	34
8. Rabbits	0	4	0	0	4
9. Non-human Primates	0	0	0	0	0
10. Sheep	56	128	83	0	211
11. Pigs	6	476	0	699	1175
12. Other Farm Animals	9	323	21	63	407
13. Other Animals	9234	719	3213	7	3939

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
01-FEB-2018

APHIS FORM 7023
JUL 2013

OMB APPROVED
0579-0036

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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
42-G-0001

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

National Animal Disease Center
P.O. Box 70

AMES, IA 50010

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)**
MICE	8913	16	3154	0	3170
RATS	0	34	0	0	34
GOATS	10	0	17	0	17
RACCOONS	0	0	15	0	15
WHITETAILED DEER	61	132	19	0	151
ELK	2	45	0	0	45
BISON	0	39	8	0	47
TURKEY	248	453	0	7	460

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
01-FEB-2018

APHIS FORM 7023A
AUG 2013

Column E Explanation

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 a lay persons as well as scientists.

1. Registration Number: 42-G-0001

2. Number _34 (22 in Cat E)_____ of animals in this study.

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

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

Hamsters may be inoculated with leptospires using culture medium, liquid culture or tissue homogenate in transport medium administered intraperitoneally inoculation of live leptospires.

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)

The observation of clinical signs and their stage of advancement will be used to indicate euthanasia. Alleviating or relieving these signs will interfere with assessment. No alternatives to the painful procedure were identified which will allow evaluation of leptospiral virulence. Animals will be weighed once daily beginning on day of inoculation, weight loss of >10% or development of outward clinical signs (observable hemorrhage, ruffled hair coat and isolation, loss of interest in food and water) will warrant euthanasia. (Haake. Current Protocols in Microbiology, 2006 Supp. 2, 12E.2.1)

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): None

1. Registration Number: 42-G-0001

2. Number _4 (2 in Cat E)_____ of animals in this study.

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

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

Guinea pigs may be inoculated with leptospira using culture medium, liquid culture or tissue homogenate in transport medium administered intraperitoneally.

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)

Column E Explanation

The observation of clinical signs and their stage of advancement will be used to indicate euthanasia. Alleviating or relieving these signs will interfere with assessment. Variation in virulence among isolates prohibits the use of specific time frames to indicate progression of disease, the use of observable clinical signs including measured weight loss, evidence of hemorrhage, appearance of ruffled hair coat and isolation, observable loss of interest in food and water allow disease progression to be monitored and the decision to euthanize to be made in a timely manner. No alternatives to the painful procedure were identified which will allow evaluation of leptospiral virulence. Animals will be weighed once daily beginning on day of inoculation, weight loss of >20% or development of outward clinical signs (observable hemorrhage, ruffled hair coat and isolation, loss of interest in food and water) will warrant euthanasia.

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): None

1. Registration Number: 42-G-0001

2. Number _304 (163 in Cat E) _____ of animals in this study.

3. Species (common name) Pigs of animals used in the study.

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

Intranasal inoculation with Porcine Reproductive and Respiratory Syndrome Virus; or a single porcine respiratory disease complex (PRDC) pathogen or their deletion mutants.

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)

To evaluate the pathogenicity of a virus or bacterial isolate/mutant, or the efficacy of intervention strategies such as vaccination, we will need to evaluate host response which precludes the use of drugs that might alleviate clinical signs thus masking the true pathogenic nature of the inoculum. If severe illness occurs animals will be euthanized.

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): None

1. Registration Number: 42-G-0001

2. Number _475 (304 in Cat E) _____ of animals in this study.

3. Species (common name) Pigs of animals used in the study.

Column E Explanation

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

Intranasal inoculation with influenza A viruses will use physical restraint of the pig and inoculum will be dripped into each nostril. Intratracheal inoculation with influenza A viruses will require anesthetizing the pig. Inoculum will be passed into the trachea via a small plastic tube.

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)

Only mild clinical signs are anticipated following infection with influenza A viruses. Since the use of drugs would mask the clinical signs of influenza illness, evaluation of clinical signs without the use of drugs is required to meet the project objectives of IAV pathogenesis, transmission, and host response in swine.

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): None

1. Registration Number: 42-G-0001

2. Number _130 (98 in Cat E)_____of animals in this study.

3. Species (common name) Pigs_____of animals used in the study.

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

Phosphate buffered saline containing Salmonella Typhimurium strain will be administered intranasally.

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)

The use of exogenous antibiotics or pain-relieving drugs may affect results of the study, which are to characterize the effects of industry-relevant antibiotics on the intestinal microbiome of pigs colonized with multidrug-resistant salmonella or to evaluate the protection provided by an attenuated Salmonella enterica serovar Typhimurium vaccine against subsequent exposure to virulent strains of Salmonella enterica, and confound interpretation of the data.

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): None

1. Registration Number: 42-G-0001

Column E Explanation

2. Number _60 (30 in Cat E)_____of animals in this study.

3. Species (common name)__Pigs_____of animals used in the study.

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

Pigs will be physically restrained and gavaged with Brachyspira hyodysenteriae into the stomach.

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)

Administration of drugs or ameliorative treatments may modify or mask the impact of the feed additive under study by mitigating the presence of disease in pigs receiving the non-amended diet. There is a complex interaction between the animal immune system, microbiota and B. hyzdysenteriae and mediating at one of these levels will limit interpretation of the results.

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): None

1. Registration Number:___42-G-0001_____

2. Number _92 (72 in Cat E)_____of animals in this study.

3. Species (common name)__Pigs_____of animals used in the study.

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

Phosphate buffered saline containing B Bordetella bronchiseptica will be administered intranasally. Some pigs will have a follow up inoculation a week after initial challenge of phosphate buffered saline containing Pasteurella multocida, Haemophilus parasuis, or Streptococcus suis.

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)*

The purpose of the proposed work is to evaluate the pathogenicity/virulence of the isolates/mutants of Bordetella as well as their interaction with other pathogens. Drugs may alter these interactions and thus will not be used.

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): None

1. Registration Number:___42-G-0001_____

Column E Explanation

2. Number _42 (32 in Cat E)_____of animals in this study.

3. Species (common name)__Pigs_____of animals used in the study.

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

Intranasal challenge of pigs with Seneca Valley virus (SVV).

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)

Three part answer: 1) To study the pathogenesis of the SVA infection in swine, the host response has to be "normal," no alterations from extraneous treatments. 2) If drugs would be beneficial in reducing pain/distress, then they would have some effect on the pig's response which alters the pathogenesis of the virus. 3) To evaluate the potential efficacy of a vaccine or treatment, the natural expression of the disease is necessary.

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): None

1. Registration Number:__42-G-0001_____

2. Number _ 322 (7 in Cat E)_____of animals in this study.

3. Species (common name)__Turkeys_____of animals used in the study.

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

Bolton's broth containing genetically modified (antibiotic-resistant) Campylobacter jejuni or Campylobacter coli, or wild type (unmodified) Campylobacter jejuni or Campylobacter coli will be orally gavaged into the crop of poults.

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)

Campylobacter jejuni or C. coli infection alone does not directly cause morbidity or mortality in turkey poults. However, it is possible that other opportunistic pathogens present in the intestinal tract may take advantage of dysbiosis created by Campylobacter colonization, causing morbidity (e.g., watery diarrhea) severe enough to warrant euthanasia. Because the goals of this animal experiment are to 1) compare host-gene expression in poults with or without Campylobacter colonization, 2) quantify the burden of Campylobacter colonization in the lower intestinal tract and 3) determine the effect of an in feed antibiotic (BMD) to affect Campylobacter colonization,

Column E Explanation

all Campylobacter inoculated poults (n=275) have been placed in category E. The use of antimicrobial or anti-inflammatory agents to treat Campylobacter-induced morbidity may affect intestinal colonization by Campylobacter, and impact host gene expression or the composition of the intestinal microbiome. Any antimicrobial or anti-inflammatory therapy will confound data analysis and the ability to draw conclusions.

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):

1. Registration Number: 42-G-0001

2. Number _16 (12 in Cat E)_____of animals in this study.

3. Species (common name) Cattle of animals used in the study.

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

Aerosol challenge with bovine respiratory syncytial virus (BRSV).

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)

Because these studies are designed to examine the efficacy of a novel vaccine to protect against virulent BRSV challenge, delivery of pain relieving drugs could alter the outcome of the experimental challenge, by modulation of disease progression

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): None

1. Registration Number: 42-G-0001

2. Number _64 (8 in Cat E)_____of animals in this study.

3. Species (common name) Cattle of animals used in the study.

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

Dairy calves and cows will be maintained in an on-site herd to allow study of paratuberculosis in subclinical and clinical stages of disease. It is critical that animals are housed as typical dairy cattle, undergoing stressors of gestation, parturition, and lactation in order to progress from subclinical to clinical disease.

Column E Explanation

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)

The use of drugs will change the natural course of disease progression and alter the interpretation of the results but in cases of standard veterinary care analgesics will be used.

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):None

1. Registration Number: 42-G-0001

2. Number _16 (12 in Cat E)_____of animals in this study.

3. Species (common name) Cattle _____of animals used in the study.

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

Bovine viral diarrhea virus will be administered intranasally and Mycoplasma bovis will be deposited using intratracheal or intranasally inoculation. Cattle inoculation with one agent will be given the other agent 6 days to 3-4 weeks later.

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)

Typical treatment would include anti-inflammatories but treatment with these drugs could augment shedding patterns of the pathogens. Altered shedding patterns may interfere with the transmission of the disease and pathogenesis which is the purpose for this study and therefore cannot be administered.

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): None

1. Registration Number: 42-G-0001

2. Number _16 (6 in Cat E)_____of animals in this study.

3. Species (common name) Cattle _____of animals used in the study.

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

Intranasal inoculation with typical virulence bovine viral diarrhea virus.

Column E Explanation

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)

Typical treatment would include anti-inflammatories but treatment with these drugs could augment shedding patterns of the pathogen. Altered shedding patterns may interfere with the transmission of the disease which is the purpose for this study and therefore cannot be administered.

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): None

1. Registration Number: 42-G-0001

2. Number _18 (14 in Cat E)_____ of animals in this study.

3. Species (common name) Cattle _____ of animals used in the study.

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

Bovine herpesvirus 4 will be administered intranasally.

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)

Typical treatment would include anti-inflammatories but treatment with these drugs could augment shedding patterns of the pathogen. Altered shedding patterns may interfere with the transmission of the disease and pathogenesis which is the purpose for this study and therefore cannot be administered.

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): None

1. Registration Number: 42-G-0001

2. Number _11 (11 in Cat E)_____ of animals in this study.

3. Species (common name) Cattle _____ of animals used in the study.

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

Cattle will be infected with a mastitis-causing pathogen (e.g. E. coli, S. uberis, or S. aureus) in one quarter of the mammary gland.

04 DEC 2017

Column E Explanation

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)

Treatment (antibiotics) cannot be given because this will not allow the disease to progress in an experiment. Use of pain drugs affect the immune system and should not be used. Two exceptions are: (1) Animals that have a rectal temperature of greater than 106F will be immediately treated for fever as recommended by veterinarian or delegate. (2) Animals that have a rectal temperature of greater than 104.5F for two consecutive observations will be treated for fever as recommended by veterinarian or delegate.

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): None