OMB APPROVED
0579-0036

Interagency Report Control No. 0180-DOA-AN

Fiscal year: 2022

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

Annual Report of Research Facility
Column E Explanation

(TYPE OR PRINT)

This information is required by law (7 U.S.C. 2143 and 9 C.F.R. §2.36). Failure to report according to the regulations can result in an order to cease and desist.

1. REGISTRATION NUMBER

42-G-0001

2. Research Facility Headquarters address

P.O. Box 70
Ames, IA 50010

3. Number of animals used in the study.

4 (2 in Cat. E)

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

Guinea Pigs

5. Explain theprocedure producing pain and distress.

Guinea Pigs may be inoculated with live leptospires.

6. Provide the scientific justification for not providing the appropriate anesthetics, analgesics or tranquilizing drugs during procedures where the animal experienced accompanying pain or distress greater than momentary or slight.

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.

7. 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

Agency	CFR

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1. REGISTRATION NUMBER

42-G-0001

2. Research Facility Headquarters address

P.O. Box 70
Ames, IA 50010

3. Number of animals used in the study.

45 (14 in Cat. E)

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

Hamsters

5. Explain the procedure producing pain and distress.

Hamsters may be inoculated with live leptospires.

6. Provide the scientific justification for not providing the appropriate anesthetics, analgesics or tranquilizing drugs during procedures where the animal experienced accompanying pain or distress greater than momentary or slight.

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.

7. 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

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1. REGISTRATION NUMBER

42-G-0001

2. Research Facility Headquarters address

P.O. Box 70
Ames, IA 50010

3. Number of animals used in the study.

117 (6 in Cat. E)

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

Sheep

5. Explain the procedure producing pain and distress.

Inoculation with transmissible spongiform encephalopathy (TSE).

6. Provide the scientific justification for not providing the appropriate anesthetics, analgesics, or tranquilizing drugs during procedures where the animal experienced accompanying pain or distress greater than momentary or slight.

Drugs will be used to alleviate pain and distress that occurs during procedures or due to intercurrent disease. Animals are requested in category E due to the potential that they will exhibit clinical signs as a result of being inoculated with a prion disease agent. Currently, there are no known treatments for prion disease.

7. 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

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2. Research Facility Headquarters address

P.O. Box 70
Ames, IA 50010

3. Number of animals used in the study.

64 (46 in Cat. E)

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

Pigs

5. Explain the procedure producing pain and distress.

Intranasal inoculation of pigs with porcine reproductive and respiratory syndrome virus (PRRSV).

6. Provide the scientific justification for not providing the appropriate anesthetics, analgesics, or tranquilizing drugs during procedures where the animal experienced accompanying pain or distress greater than momentary or slight.

Clinical signs are a measure of the degree of vaccine protection from clinical disease in the challenged pigs and the use of drugs could mask the expression of clinical signs..

7. 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

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2. Research Facility Headquarters address

P.O. Box 70
Ames, IA 50010

3. Number of animals used in the study.

90 (89 in Cat. E)

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

Pigs

5. Explain the procedure producing pain and distress.

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

6. Provide the scientific justification for not providing the appropriate anesthetics, analgesics, or tranquilizing drugs during procedures where the animal experienced accompanying pain or distress greater than momentary or slight.

The purpose of the proposed work is to evaluate the pathogenicity/virulence of the isolates/mutants of these pathogens as well as host response following infection. Drugs such as antibiotics that are typically used to treat these infections will clear the infection and alter the course of disease. Anti-inflammatory and pain-relieving drugs can mask clinical signs which we are monitoring and recording as well as alter the host response to infection.

7. 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

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42-G-0001

2. Research Facility Headquarters address

P.O. Box 70
Ames, IA 50010

3. Number of animals used in the study.

88 (80 in Cat. E)

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

Pigs

5. Explain the procedure producing pain and distress.

Intranasal or intratracheal inoculation with Highly Pathogenic Avian Influenza (HPAI).

6. Provide the scientific justification for not providing the appropriate anesthetics, analgesics, or tranquilizing drugs during procedures where the animal experienced accompanying pain or distress greater than momentary or slight.

No clinical signs are anticipated following infection with HPAI. 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.

7. 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

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1. REGISTRATION NUMBER

42-G-0001

2. Research Facility Headquarters address

P.O. Box 70
Ames, IA 50010

3. Number of animals used in the study.

365(275 in Cat. E)

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

Pigs

5. Explain the procedure producing pain and distress.

Inoculation with influenza A viruses.

6. Provide the scientific justification for not providing the appropriate anesthetics, analgesics, or tranquilizing drugs during procedures where the animal experienced accompanying pain or distress greater than momentary or slight.

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.

7. 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

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1. REGISTRATION NUMBER

42-G-0001

2. Research Facility Headquarters address

P.O. Box 70
Ames, IA 50010

3. Number of animals used in the study.

6 (6 in Cat. E)

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

Pigs

5. Explain the procedure producing pain and distress.

Inoculation of tissue homogenate prepared from field sample(s), or with a cell culture preparation that contains an infectious filterable agent isolated from swine.

6. Provide the scientific justification for not providing the appropriate anesthetics, analgesics, or tranquilizing drugs during procedures where the animal experienced accompanying pain or distress greater than momentary or slight.

If efficacious pain-relieving drugs or other ameliorative treatments were used, they would mask clinical signs which would obscure the evaluation of reproducing the disease observed in the field. The proposed studies require the evaluation of infectivity of the potential unknown virus, and pathogenesis of the disease which requires the disease to progress naturally, thus unaffected by drugs.

7. 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

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42-G-0001

2. Research Facility Headquarters address

P.O. Box 70
Ames, IA 50010

3. Number of animals used in the study.

60 (46 in Cat. E)

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

Pigs

5. Explain the procedure producing pain and distress.

Intranasal or oral inoculation of pigs with Senecavirus A (SVA).

6. Provide the scientific justification for not providing the appropriate anesthetics, analgesics, or tranquilizing drugs during procedures where the animal experienced accompanying pain or distress greater than momentary or slight.

To evaluate the potential efficacy of a vaccine, the natural expression of the disease is necessary and drugs beneficial for reducing pain/distress may alter the pig's immune response.

7. 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

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42-G-0001

2. Research Facility Headquarters address

P.O. Box 70
Ames, IA 50010

3. Number of animals used in the study.

20 (10 in Cat. E)

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

Pigs

5. Explain the procedure producing pain and distress.

Oronasal inoculation of pigs with Salmonella enterica serotype Typhimurium.

6. Provide the scientific justification for not providing the appropriate anesthetics, analgesics, or tranquilizing drugs during procedures where the animal experienced accompanying pain or distress greater than momentary or slight.

The validity of the experimental results requires colonization by S. Typhimurium without the use of therapeutic drugs. Antimicrobials may decrease the colonization level of Salmonella and cause changes to the swine gut microbiome, which will alter the interactions and transfer of genes between S. Typhimurium and the commensal gastrointestinal microbiota.

7. 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

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1. REGISTRATION NUMBER

42-G-0001

2. Research Facility Headquarters address

P.O. Box 70
Ames, IA 50010

3. Number of animals used in the study.

40 (27 in Cat. E)

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

Cattle

5. Explain the procedure producing pain and distress.

Naturally infected 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.

6. Provide the scientific justification for not providing the appropriate anesthetics, analgesics, or tranquilizing drugs during procedures where the animal experienced accompanying pain or distress greater than momentary or slight.

The use of drugs may change the natural course of disease progression and alter the interpretation of the results but in cases of unrelated ailments analgesics may be used with prior consultation of the clinical veterinarian and researcher.

7. 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

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42-G-0001

2. Research Facility Headquarters address

P.O. Box 70
Ames, IA 50010

3. Number of animals used in the study.

4 (4 in Cat. E)

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

Cattle

5. Explain the procedure producing pain and 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.

6. Provide the scientific justification for not providing the appropriate anesthetics, analgesics, or tranquilizing drugs during procedures where the animal experienced accompanying pain or distress greater than momentary or slight.

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 unless animals have a rectal temperature of greater than 106F. Those animals will be immediately treated for fever as recommended by veterinarian or delegate. Animals that have a rectal temperature of greater than 104.5F for two consecutive observations will be treated for fever as recommended by veterinarian.

7. 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

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1. REGISTRATION NUMBER

42-G-0001

2. Research Facility Headquarters address

P.O. Box 70
Ames, IA 50010

3. Number of animals used in the study.

36 (4 Cat. E)

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

Cattle

5. Explain the procedure producing pain and distress.

Exposure to transmissible spongiform encephalopathy prion material by various routes.

6. Provide the scientific justification for not providing the appropriate anesthetics, analgesics, or tranquilizing drugs during procedures where the animal experienced accompanying pain or distress greater than momentary or slight.

Drugs will be given to alleviate pain/distress for any non-TSE intercurrent disease. Since there are no known treatments for clinical neurologic signs associated with the development of TSE's, any animals that may develop neurologic signs have been requested in category E.

7. 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

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1. REGISTRATION NUMBER

42-G-0001

2. Research Facility Headquarters address

P.O. Box 70
Ames, IA 50010

3. Number of animals used in the study.

14 (14 in Cat. E)

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

Cattle

5. Explain the procedure producing pain and distress.

Cattle will be orally and intranasally vaccinated with Mannheimia haemolytica.

6. Provide the scientific justification for not providing the appropriate anesthetics, analgesics or tranquilizing drugs during procedures where the animal experienced accompanying pain or distress greater than momentary or slight.

Typical treatment would include anti-inflammatories but treatment with these drugs could affect efficacy of vaccine. Therefore pain-relieving drugs cannot be administered.

7. 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

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1. REGISTRATION NUMBER

42-G-0001

2. Research Facility Headquarters address

P.O. Box 70
Ames, IA 50010

3. Number of animals used in the study.

28 (28 Cat. E)

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

Cattle

5. Explain the procedure producing pain and distress.

Cattle will be challenged with Mycobacterium bovis via aerosol mask.

6. Provide the scientific justification for not providing the appropriate anesthetics, analgesics, or tranquilizing drugs during procedures where the animal experienced accompanying pain or distress greater than momentary or slight.

The only measure of vaccine-induced protection is the postmortem determination of disease severity. As such, interventions which alter the immune response directly impact disease severity adding undesirable and poorly defined variables to the study.

7. 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):

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42-G-0001

2. Research Facility Headquarters address

P.O. Box 70
Ames, IA 50010

3. Number of animals used in the study.

10 (6 in Cat. E)

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

Cattle

5. Explain the procedure producing pain and distress.

Intranasal inoculation with Senecavirus A.

6. Provide the scientific justification for not providing the appropriate anesthetics, analgesics, or tranquilizing drugs during procedures where the animal experienced accompanying pain or distress greater than momentary or slight.

Typical treatment would include anti-inflammatories but treatment with these drugs could augment shedding patterns of the pathogen as well as immune responses.
Altered shedding patterns and immune responses may interfere with overall conclusions about disease progression and pathogenesis which is the purpose for this study and therefore cannot be administered.

7. 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

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42-G-0001

2. Research Facility Headquarters address

P.O. Box 70
Ames, IA 50010

3. Number of animals used in the study.

48 (38 in Cat. E)

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

Ferret

5. Explain the procedure producing pain and distress.

Intranasal inoculation of Influenza A virus.

6. Provide the scientific justification for not providing the appropriate anesthetics, analgesics, or tranquilizing drugs during procedures where the animal experienced accompanying pain or distress greater than momentary or slight.

We anticipate only mild clinical signs following infection with IAV. 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 ferrets.

7. 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

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42-G-0001

2. Research Facility Headquarters address

P.O. Box 70
Ames, IA 50010

3. Number of animals used in the study.

30 (18 in Cat. E)

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

Mink

5. Explain the procedure producing pain and distress.

Intranasal inoculation with SARS-CoV-2.

6. Provide the scientific justification for not providing the appropriate anesthetics, analgesics, or tranquilizing drugs during procedures where the animal experienced accompanying pain or distress greater than momentary or slight.

The proposed studies require the evaluation of the pathogenesis of the disease which requires the disease to progress naturally, thus unaffected by drugs.

7. 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

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42-G-0001

2. Research Facility Headquarters address

P.O. Box 70
Ames, IA 50010

3. Number of animals used in the study.

65 (65 in Cat. E)

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

Mouse

5. Explain the procedure producing pain and distress.

Inoculation with Histophilus somni.

6. Provide the scientific justification for not providing the appropriate anesthetics, analgesics, or tranquilizing drugs during procedures where the animal experienced accompanying pain or distress greater than momentary or slight.

Typical treatment to control H. somni infection would include antibiotics such as Excenel, Nuflor, and Baytril. However, treatment of mice with these antibiotics will affect the disease pathogenesis. Therefore antibiotics cannot be administered but, mice will be euthanized immediately when they show clinical signs of septicemia.

7. 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

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42-G-0001

2. Research Facility Headquarters address

P.O. Box 70
Ames, IA 50010

3. Number of animals used in the study.

2380 (1311 in Cat. E)

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

Mouse

5. Explain the procedure producing pain and distress.

Inoculation with transmissible spongiform encephalopathy (TSE).

6. Provide the scientific justification for not providing the appropriate anesthetics, analgesics, or tranquilizing drugs during procedures where the animal experienced accompanying pain or distress greater than momentary or slight.

Drugs can be used to alleviate pain and distress associated with treatments or concurrent illness. Some mice are expected to develop clinical signs of prion disease for which there is no treatment.

7. 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

Agency	CFR

OMB APPROVED
0579-0036

Interagency Report Control No. 0180-DOA-AN

Fiscal year: 2021

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

Annual Report of Research Facility
Column E Explanation

(TYPE OR PRINT)

This information is required by law (7 U.S.C. 2143 and 9 C.F.R. §2.36). Failure to report according to the regulations can result in an order to cease and desist.

1. REGISTRATION NUMBER

42-G-0001

2. Research Facility Headquarters address

P.O. Box 70
Ames, IA 50010

3. Number of animals used in the study.

379 (204 in Cat. E)

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

Chickens

5. Explain the procedure producing pain and distress.

Chickens inoculated by oral gavage with Salmonella enterica serotype Heidelberg.

6. Provide the scientific justification for not providing the appropriate anesthetics, analgesics, or tranquilizing drugs during procedures where the animal experienced accompanying pain or distress greater than momentary or slight.

Birds will be group housed, so individual treatment will be difficult since birds cannot be easily isolated or tracked. If an infection is suspected, antibiotic administration would negatively impact the results of the experiment. For both reasons, birds will be euthanized if they are in distress, or fail rise and move when prodded.

7. 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

Agency	CFR

OMB APPROVED
0579-0036

Interagency Report Control No. 0180-DOA-AN

Fiscal year: 2022

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

Annual Report of Research Facility
Column E Explanation

(TYPE OR PRINT)

This information is required by law (7 U.S.C. 2143 and 9 C.F.R. §2.36). Failure to report according to the regulations can result in an order to cease and desist.

1. REGISTRATION NUMBER

42-G-0001

2. Research Facility Headquarters address

P.O. Box 70
Ames, IA 50010

3. Number of animals used in the study.

385 (285 in Cat. E)

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

Turkeys

5. Explain the procedure producing pain and distress.

Inoculation with Salmonella.

6. Provide the scientific justification for not providing the appropriate anesthetics, analgesics, or tranquilizing drugs during procedures where the animal experienced accompanying pain or distress greater than momentary or slight.

The validity of the experimental results requires that the Salmonella enterica outbreak isolates be allowed to colonize without the use of therapeutic drugs.

7. 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

Agency	CFR

OMB APPROVED
0579-0036

Interagency Report Control No. 0180-DOA-AN

Fiscal year: 2021

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

Annual Report of Research Facility
Column E Explanation

(TYPE OR PRINT)

This information is required by law (7 U.S.C. 2143 and 9 C.F.R. §2.36). Failure to report according to the regulations can result in an order to cease and desist.

1. REGISTRATION NUMBER

42-G-0001

2. Research Facility Headquarters address

P.O. Box 70
Ames, IA 50010

3. Number of animals used in the study.

24 (24 in Cat. E)

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

White-tailed Deer

5. Explain the procedure producing pain and distress.

Inoculation with SARS-CoV-2.

6. Provide the scientific justification for not providing the appropriate anesthetics, analgesics, or tranquilizing drugs during procedures where the animal experienced accompanying pain or distress greater than momentary or slight.

The proposed studies aim to evaluate the pathogenesis of the disease, which requires the disease to progress naturally, thus unaffected by therapeutic intervention.

7. 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

Agency	**CFR**