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. Annual Reports and explanations should NOT include PII information such as names (principle investigators and research staff), addresses, protocols, meeting notes (either in part or in full), the animal room numbers, grant information, veterinary care programs and the like. A Column E explanation must be written so as to be understood by a lay persons as well as scientists.

1. Registration Number:___ 42-F-0008_____

2. Number _92 (25 in Cat E)_____of animals in this study.

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

4. Explain the procedure producing pain and/or distress. Explanations should include a brief description of the procedure, but also explain what the animal's experience, examples of which may include, but are not limited to: Neurological signs, seizures, tremors, paralysis, lethargy, inappetance, respiratory signs, GI distress, vomiting, and diarrhea.

Evaluation of Leptospira Bacterins and maintenance of challenge cultures cause animals to experience Leptospirosis. Hamsters inoculated intraperitoneally, intramuscularly, or subcutaneously with leptospira can develop outward clinical signs (observable hemorrhage, ruffled hair coat, weight loss, lethargy, and isolation).

5. Attach or include with the reason(s) for why anesthetics, analgesics and tranquillizers could not be used. (For Federally mandated testing, see Item 6 below)

Drugs may affect the progression of clinical disease. The Leptospira potency tests mandated by the 9CFR use death as an endpoint; however, in accordance with 9 CFR 117.4 and CVB Notice 12-12, hamsters that are observed in a moribund state will be euthanized after consultation with the contact person and counted as dead. Disease progression may be rapid and animals may not be observed in this state.

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): If the requirement is per a guidance document, such as an Agency notice or harmonization guideline, please provide specific sufficient information to identify the cited document.

APHIS, 9CFR 113.101, 113.102, 113.103, and 113.104 which are all Leptospirosis tests.

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1. Registration Number:___ 42-F-0008_____

2. Number _121 (31 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. Explanations should include a brief description of the procedure, but also explain what the animal's experience, examples of which may include, but are not limited to: Neurological signs, seizures, tremors, paralysis, lethargy, inappetance, respiratory signs, GI distress, vomiting, and diarrhea.

Potency testing of tetanus toxoids and antitoxins - an animal getting insufficient protection from the tetanus antitoxin becomes sick from tetanus toxin challenge. Guinea pigs are injected subcutaneously in the ventrolateral abdominal area with toxin-antitoxin mixture. Clinical signs progress from tight back end, to curvature of the back, pronounced curvature and hopping, extensor muscle paralysis and finally inability to rise.

5. Attach or include with the reason(s) for why anesthetics, analgesics and tranquillizers could not be used. (For Federally mandated testing, see Item 6 below)

Pain relieving drugs cannot be used because they will interfere with the interpretation of the test. However, in accordance with 9CFR 117.4 and CVB Notice 12-12, animals that are observed in a moribund state will be euthanized after consultation with the contact person and counted as dead. Disease progression could be rapid and animals may not be observed in this state. Observation frequency will increase once clinical signs are noted.

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): If the requirement is per a guidance document, such as an Agency notice or harmonization guideline, please provide specific sufficient information to identify the cited document.

APHIS, 9CFR 113.114 and 113.451

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1. Registration Number:___ 42-F-0008_____

2. Number _ 60 (5 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. Explanations should include a brief description of the procedure, but also explain what the animal's experience, examples of which may include, but are not limited to: Neurological signs, seizures, tremors, paralysis, lethargy, inappetance, respiratory signs, GI distress, vomiting, and diarrhea.

Guinea pigs are challenged intramuscularly with a suspension of Clostridium chauvoei, C. haemolyticum, or C. septicum. Animals become ill from challenge with these organisms. Clinical signs include swelling or focal lesion at the injection site.

5. Attach or include with the reason(s) for why anesthetics, analgesics and tranquillizers could not be used. (For Federally mandated testing, see Item 6 below)

Pain relieving drugs cannot be used because they will interfere with the interpretation of the test. However, in accordance with 9CFR 117.4 and CVB Notice 12-12, if guinea pigs observed in a moribund state, they will be euthanized after consultation with the contact person and counted as dead. Disease progression could be rapid and animals may not be observed during this state.

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): If the requirement is per a guidance document, such as an Agency notice or harmonization guideline, please provide specific sufficient information to identify the cited document.

APHIS, 9 CFR 113.106 and 113.107

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