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-F-0008

2. Number 2515 (428 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.

Evaluation of Leptospira Bacterins and maintenance of challenge cultures cause animals to experience Leptospirosis.

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)

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, 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):

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

FY 2012

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1. Registration Number: 42-F-0008

2. Number 62 (23 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.

Potency testing of tetanus toxoids and antitoxins - an animal getting insufficient protection from the tetanus antitoxin becomes sick from tetanus toxin challenge.

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)

Pain relieving drugs cannot be used because they will interfere with the interpretation of the test. However, in accordance with 9CFR 117.4, 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.

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):

   APHIS, 9CFR 113.114 and 113.451

FY2012

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1. Registration Number: 42-F-0008

2. Number 92 (12 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.

Clostridium chauvoei, C. haemolyticum, and C. septicum challenge tests- animals become ill from challenge with these organisms.

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)

Pain relieving drugs cannot be used because they will interfere with the interpretation of the test. However, in accordance with 9CFR 117.4, if guinea pigs 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 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):

APHIS, 9 CFR 113.106 and 113.107

FY 2012

NOV - 6 2012