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 lay persons as well as scientists.

1. Registration Number: 14- R - 0164

2. Number 594 of animals used in this study.

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

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

   This protocol contains a standard model to test C. Difficile infection and therapeutic usage. The model creates severe infection in which vehicle or low treated antibiotic control groups will be more likely to succomb. As death is _not_ an endpoint, humane endpoints are put in place, however not all animals are caught by monitoring prior to becoming moribund.

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)

   In order to test efficacy of therapeutics, an infection must be created. Treatment of the infection to alleviate pain and/or distress would not allow for valid screening of the therapeutic agent. A clinical assessment scoring is used to monitor all animals, thereby euthanizing animals that start to show signs of depression or lethargy.

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_____ CFR_____

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