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## 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: 33-V-0004 / 554
2. Number 88 (Category E) 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.

Animals are given an oral dose of *Clostridium difficile*.

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)

This experiment is designed to investigate the effects of toxin variant strains. Although every effort is made to identify and euthanize animals that become ill following the *C.difficile* infection, there are some animal that may die naturally very suddenly without prior evidence of illness or distress, despite frequent observation. Because not all such animals can be identified by us, and we cannot predict with certainty how many animals will become ill, we have placed all of these animals in USDA category E.

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 N/A CFR

NP 11/25/2011

Obtained by Rise for Animals.