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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 9 (Category E) _____ of animals used in this study.
3. Species (common name) Hamster 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 use to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see Item 6 below).

Although every effort is made to identify and euthanize animals that become ill following *C. difficile* infection, there are some animals that die naturally very suddenly (presumably because of systemic dissemination of *C. difficile* toxin) without prior evidence of illness or distress, despite frequent observation. Animals will be monitored three times daily for 2 weeks, then daily until the end of the experiment. While some animals with mild symptoms are able to survive challenge with a toxin-variant strain, mortality is an unavoidable endpoint for some animals in these experiments that are designed to investigate the effects of toxin variant strains.

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 _____