

LRI Study No. 16.0805.009

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: 21 - R - 0173
2. Number 30 total / 30 category E of animals used in this study.
3. Species (common name) Canine of animals used in the study.
4. Explain the procedure producing pain and/or distress.

Animals were administered live Canine Distemper Virus (CDV) to elicit clinical signs of the illness.

5. Provide a 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)

As per 9CFR113.306, clinical disease must be allowed to prove pathology of the challenge dose of CDV to confirm the virulence of the challenge material in unvaccinated mini mongrels. Effective pain relieving agents would mask the clinical signs. However, animals were monitored at least twice daily including weekends and holidays. If it were suspected that symptoms may become severe after normal working hours, technicians would be on site after hours for monitoring purposes. If any animal's condition prolonged or failed to improve, veterinary intervention was escalated.

6. What, if any, federal regulations require this procedure? Cite the agency, the code of Federal Regulations (CFR) title number and the specified section number (e.g., AHPIS, 9 CFR 113.102):

Agency APHIS 9 CFR 113.306

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