

### Column E Explanation

1. Iowa State University; Registration Number – 42-R-0003
2. Total number of animals used in the study: 2 in study; 1 in Column E
3. Species (common name) used in study: Dogs
4. Explain the procedure producing pain and/or distress:

Two foxhounds with naturally occurring *Leishmania infantum* infection were used for this study. *Leishmania infantum* is a potentially fatal disease. It can cause visceral or organ based lesions that progress slowly over time and enlargement of lymph nodes, liver, and spleen. One of the two affected foxhounds exhibited lymph node enlargement and was placed in Category (Column) D. Additional clinical signs once an animal reaches the clinical phase include weight loss, bloody noses, crusty patches of skin, dull rough coat, kidney failure, and liver failure. One of the two affected foxhounds had begun to exhibit some of these symptoms and was placed in Category (Column) E.

5. Justification why pain and distress could not be relieved. State method or means used to determine that pain and/or distress relief would interfere with test results.

As this study examines the factors to determine progression to clinical disease, it is critical to not treat the dogs with naturally occurring *Leishmania*. Part of the study measures various aspects of the host response to *Leishmania* infection, therefore the disease must be allowed to progress with no accompanying treatments to reduce lesion size. In the current literature in this field, no alternative to in vivo studies have been described or are appropriate for studying the host-pathogen interaction of infection. One of the two foxhounds that had naturally occurring *Leishmania* was placed in Category (Column) E because of clinical anemia; sporadic melena (blood in stool); persistent dull, thin hair coat on legs, muzzle, and around eyes; and hygromas on a few bony prominences. Palliative therapy of an elevated dog bed was used. These two dogs were euthanized before clinical signs of kidney or liver function were present.

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:

Not required by Federal Regulations.

12/20 ✓