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: 1664

2. Number 4 of animals used in this study.

3. Species (common name) Guinea Pig of animals used in this study.

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

   Vena cava blood draw

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 would interfere with test results (for federally mandated testing, see item 6 below).

   As the vena cava blood draw procedure in guinea pigs is a blind stick, unintended errors may cause adverse reactions that may include respiratory distress, abnormal chest sounds, lethargy, hunched posture, oral/nasal discharge or pale mucus membranes. If any of these indicators appear quickly, they will be addressed immediately. However, these indicators may also occur between monitoring sessions or overnight. Although unintended, if any recovered animal experiences delayed complications including unexpected death without analgesia, it will be categorized under pain category E as there will have been no pain alleviation during this period.
   Signs of possible adverse reactions from vena cava blood draws include respiratory distress, abnormal chest sounds, lethargy, hunched posture, oral or nasal discharge, pale mucus membranes and infection.

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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1. Registration Number: 1664

2. Number 1 of animals used in this study.

3. Species (common name) Pig of animals used in this study.

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

   Cardiomyopathy Model

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 would interfere with test results (for federally mandated testing, see item 6 below).

   There is the possibility that animals may develop ventricular arrhythmias leading to hemodynamic instability off hours when the ARF staff are not present during the survival period. This would result in rapid deterioration including lethargy and dyspnea. If left untreated the animal would eventually develop a lethal ventricular arrhythmia (ventricular fibrillation) where they would lose consciousness and die within 30-60 seconds of this occurrence. This may occur late in the survival period and in situations where pain medication is no longer being provided. This is an unfortunate, but necessary complication of this model and respective of the significant clinical correlation to the human pathophysiology. Animals are likely not to be in distress for more than 30-60 seconds before losing consciousness and ultimately expiring.
   Category E animals include animals that develop ventricular arrhythmias late in the survival period spontaneously during the off hours when ARF staff are not available. The clinical signs include dyspnea, lethargy, and tachycardia.

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 _____