

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: **93-R-0032**
2. Number of animals used in this study: **2**
3. Species (common name) of animals used in this study: **Pigs**
4. Explain the procedure producing pain and/or distress:

The disease being studied is coronary artery disease (CAD). The purpose of this research is to evaluate the accuracy of a newly developed cardiac magnetic resonance (CMR) technique for the myocardial blood flow measurement against the non-invasive reference method, positron emission tomography (PET). Though appropriate anesthetics, analgesics and tranquilizers are used for surgical procedures, this protocol was assigned as category E due to the potential for severe complications post-surgery that may result in mortality.

A major surgery (thoracotomy) is performed to create a pig myocardial ischemia model by placing an ameroid constrictor on the coronary artery to induce stenosis. Pain relief drugs are administered to the pig on the morning of the surgery and pigs are sedated with intra-muscular drugs prior to the procedure. IV anesthesia is then administered and once anesthetized, pigs are intubated for the duration of the surgery. After surgery, pain relief drugs are again administered as the pig wakes up from anesthesia. Based on clinical presentation, pain medication may occur 12-24 hours after surgery to be continued at 24 hour intervals as needed.

Three weeks later, pigs undergo a carotid cut down surgery to insert the coronary catheter to determine the presence and severity of stenosis under Fluoroscopy and angiography. Pain relief procedures are the same as the initial surgery.

Pigs undergo PET-MR imaging at 2 and 4 weeks after the initial surgery. An optional third PET-MR scan may be performed after 6 weeks as a non-survival procedure.

5. Attach or include an explanation with the reasons(s) for why anesthetics, analgesics and tranquilizers could not be used. (For Federally mandated testing, see item 6 below.)

As explained above, anesthetics, analgesics and tranquilizers are used for this protocol. An anticipated 30% of pigs may expire due to severe complications

involving fatal arrhythmias, myocardial infarction and thrombosis due to coronary artery occlusion. The two pigs referenced in this report died from fatal arrhythmias.

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: **Not Applicable** CFR:
7. We have no objections to the release of our Annual Report Attachments as received and do not intend to seek judicial review to bar release of our facility's Annual Report of Research Facility Column E Explanation(s) and/or Exception(s) for the 2018 USDA Report [FOIA Exemption 4, 5 U.S.C. 552(b)(4)].