## **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:74-R-0050, customer Number 1481				
2. Number <u>5</u>		_of animals used in this study.		
3. Species (common name)	Pigs	of animals used in the study.		

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

The term nonthyroidal illness syndrome (NTIS) refers to low serum thyroid hormone levels that occur during illness and starvation. It remains unclear whether NTIS is a beneficial adaptive response to reduce energy consumption, or a form of hypothyroidism (low serum thyroid hormone level) that requires treatment with thyroid hormone.

The aim of the proposal is to perform a pilot study to investigate in pigs the effect of NTIS secondary to septic shock on heart function and tissue energy reserves. Animals will be divided in 2 groups (6 animals per group), named *Control and Septic Shock*. During experimental phase all animals will be awake and not under mechanical ventilation support. LPS ((E coli 0111:B4, Sigma-Aldrich, St Louis, MO, USA)) will be administered. Under LPS the animal might suffer hypotension and hypoglycemia. Additionally, LPS dosing is expected to cause sepsis with fever, hyperventilation, diarrhea, and occasionally vomiting.

Our study will clarify if mortality for heart failure during septic shock is associated to poor energy status of heart. Also it will reveal if septic shock cause energy deficiency in other tissues. If so, it will allow the design of medical strategies to improve energy efficiency and decrease mortality during sepsis.

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

The animals are injected with lipopolysaccharide (LPS) which is an endotoxin. Although surgery related pain is taken cared with analgesics, the animal will suffer from LPS injection which cannot be taken care of due to the nature of the study.

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, 9CFR 113.102):

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