Column E Explanation

1. Registration Number*: 87-R-001*

2. Number of animals used in the study: *2*

3. Species (common name) of animals used in the study: *Pigs*

4. Explain the procedure producing pain and distress:

A partial thickness skin wound/graft procedure is performed under general anesthesia. The animals may experience unalleviated pain after partial-thickness wounding that typically lasts about 3 days. After 3 days, moderate to mild pain can persist for up to 2 weeks. However, the polymer based primary dressing has been shown to reduce pain in partial-thickness wounds.

5. Provide the scientific justification for not providing the appropriate anesthetics, analgesics, or tranquilizing drugs during procedures where the animal experienced accompanying pain or distress greater than momentary or slight.

The IACUC approved this column E activity. In this study, animals in the control groups will not be given analgesics as this would represent a confounding variable. This is necessary in order to compare the wound healing effects and analgesic efficacy of the controlled local anesthetic release compared to dressings without drug. Animals were monitored and, if necessary, veterinary intervention employed based on defined criteria outlined in the protocol.

There are no long-acting local analgesic solutions for patients with partial thickness wounds. Consequently, opioids are given to these patients, despite their numerous adverse side effects. In order to reduce patient exposure to opioids, novel analgesic solutions are needed that can effectively control pain for extended periods. In order to bring these novel therapies to the clinic, translatable animal studies are required to increase the likelihood of clinical success.

Cell cultures and ex vivo cutaneous models do not allow for the assessment of nociceptive response nor the evaluation of systemic toxicity—both of which are important endpoints in this research. There are no non-animal models available that can be used to assess analgesic/anesthetic effect of treatment, which is the primary outcome evaluated in this 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, 9 CFR 113, 102):

N/A