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**UNITED STATES DEPARTMENT OF AGRICULTURE**
**ANIMAL AND PLANT HEALTH INSPECTION SERVICE**

# Annual Report of Research Facility
# Column E Explanation

*(TYPE OR PRINT)*

**This information is required by law (7 U.S.C. 2143 and 9 C.F.R. §2.36). Failure to report according to the regulations can result in an order to cease and desist.**

**1. REGISTRATION NUMBER**
74-R-0108

**2. Research Facility Headquarters address**
Site 001

**3. Number of animals used in the study.**
25 E category used

**4. Species (common name) of animals used in the study.**
Swine

**5. Explain the procedure producing pain and distress.**

Pigs are challenged with the allergen to assess whether they have the allergic reaction or not, and if they do, then what is the extent of this allergic reaction. The allergic reaction is monitored using the below scale:

0 = no signs; 1 = immobility, lethargy, malaise, 2 = scratching, rash, coughing, gagging, stomach contractions; 3 = diarrhea, emesis; 4 = increase in respiratory rate, neck extension; 5 = forced expiration; 6 = confluent cutaneous reddening, cyanosis, anaphylaxis (adapted from *Rupa et al., Vet Immunol Immunopathol. 2008 Oct 15;125(3-4):303-14. doi: 10.1016/j.vetimm.2008.05.028.*).

A broad spectrum of allergic response can be expected, and these are expected to cause distress in the animals. If pigs show a reaction at scale 6, they would be administered epinephrine, with repeat doses every 15 min if required.

**6. 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 objective of the study is to develop a pig model for peanut allergy, and subsequently to use the model to determine treatment efficacy of microneedles coated with the peanut allergen. As such, to develop the model it is required that we challenge the animals to simulate human exposure to peanuts. Allergen challenge is also required to evaluate treatment efficacy so that reduction in allergy-score after treatment can be documented and statistically analyzed. Thus, interventio to reduce distress from allergic reaction cannot be performed. However, animals are monitored continuously for 2 hours after allergen challenge, and in the case of highest-scale allergic anaphylaxis reaction (scale 6), they will be treated with epinephrine after a period of 5 min. If we intervene prematurely, we will not know if the model has been developed and/o if microneedle treatment is effective or not.

**7. 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** N/A

**CFR** N/A