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-0108

2. Number 22 Cat E of animals used in this study.

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

4. Explain the procedure producing pain and/or 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 a previously published 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 (*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. To date we have only observed response at scales 0-3.

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 relief would interfere with test results. (For Federally mandated testing, see Item 6 below.)

   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, intervention 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 microneedle treatment is effective or not.

Animals

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 _____