Column E Explanation

This form is intended as an aid to complete the Column E explanation. It is not an official form and its use is voluntary. Annual Reports and explanations should NOT include PII information such as names (principle investigators and research staff), addresses, protocols, meeting notes (either in part of in full), the animals room numbers, grant information, veterinary care programs, and the like. A Column E explanation must be written so as to be understood by lay person as well as scientists.

1. Registration Number: 93-R-0066

2. Number 10 of animals categorized as column E used in this study.

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

4. Explain the procedure producing pain and/or distress. Explanations should include a brief description of the procedure, but also explain what the animal's experience, examples of which may include, but are not limited to: Neurological signs, seizures, tremors, paralysis, lethargy, inappetance, respiratory signs, GI distress, vomiting, and diarrhea.
   An investigator using Guinea Pigs was granted Salk IACUC approval to utilize complete Freund's adjuvant in order to elicit high affinity and avidity antibodies against inoculated epitopes. Animals were given analgesics at the time of antigen/CFA injection, however continuous pain control following injection may not be achieved when analgesic side-effects become a risk (buprenorphine and gastrointestinal stasis; NSAIDS and gastrointestinal ulceration and potential renal impairment), and residual inflammation may lead to further discomfort/pain. These animals are therefore considered category E per the animal use protocol.

5. Attach or include with the reason(s) for why anesthetics, analgesics and tranquillizers could not be used. (For federally mandated testing, see Item 6 below).
   Animals were given analgesics at the time of antigen/CFA injection, however continuous pain control following injection may not be achieved when analgesic side-effects become a risk (buprenorphine and gastrointestinal stasis; NSAIDS and gastrointestinal ulceration and potential renal impairment).

6. What, if any, federal regulation 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): If the requirement is per a guidance document, such as an Agency notice or harmonization guideline, please provide specific sufficient information to identify the cited document.

   Agency_____ CFR_____

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1. Registration Number: 93-R-0066

2. Number 35 of animals categorized as column E used in this study.

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

4. Explain the procedure producing pain and/or distress. Explanations should include a brief description of the procedure, but also explain what the animal's experience, examples of which may include, but are not limited to: Neurological signs, seizures, tremors, paralysis, lethargy, inappetance, respiratory signs, GI distress, vomiting, and diarrhea.
   An investigator using rabbits was granted Salk IACUC approval to utilize complete Freund's adjuvant in order to elicit high affinity and avidity antibodies against inoculated epitopes. Animals were given analgesics at the time of antigen/CFA injection, however continuous pain control following injection may not be achieved when analgesic side-effects become a risk (buprenorphine and gastrointestinal stasis; NSAIDS and gastrointestinal ulceration and potential renal impairment), and residual inflammation may lead to further discomfort/pain. These animals are therefore considered category E per the animal use protocol.

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   Animals were given analgesics at the time of antigen/CFA injection, however continuous pain control following injection may not be achieved when analgesic side-effects become a risk (buprenorphine and gastrointestinal stasis; NSAIDS and gastrointestinal ulceration and potential renal impairment).

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   Agency_____ CFR_____