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 3 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 to elicit high affinity and avidity antibodies against inoculated antigens. The use of CFA is associated with skin ulceration which develop during the first few days after intradermal injection but then resolve and heal over. There is typically few if any signs of pain and distress exhibited by animals, which have daily health assessments and regular physicals and weight collections to monitor health status. Injection site has been selected to minimize pain response to injections.
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).

   Alternatives to CFA have been evaluated including TiterMax and RIBI, however, they have not induced effective antibody responses in the context of proteins with highly homologous members in rabbit species. The investigator approves the use of analgesics and anesthetics, however, the IACUC determined that continuous pain control for this procedure without causing side effects by prolonged use of pain medications precluded the use of analgesics and anesthetics continuously throughout the study- therefore, drugs are used intermittently to minimize pain and distress but not continuously which leaves animals at category E.
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_____

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 4 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 to elicit high affinity and avidity antibodies against inoculated antigens. The use of CFA is associated with skin ulceration which develop during the first few days after intradermal injection but then resolve and heal over. There is typically few if any signs of pain and distress exhibited by animals, which have daily health assessments and regular physicals and weight collections to monitor health status. Injection site has been selected to minimize pain response to injections.

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).

   Drugs were not permissible for use in the animal use protocol due to the justification that anti-inflammatory/pain medications inhibit the production of antibodies if administered around the time of CFA injection. Blunting the immune response to the antigen may increase the number of total injections required to recover antibody which would increase the total pain/distress experienced by the animal.

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_____

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 3 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 to elicit high affinity and avidity antibodies against inoculated antigens. The use of CFA is associated with skin ulceration which develop during the first few days after intradermal injection but then resolve and heal over. There is typically few if any signs of pain and distress exhibited by animals, which have daily health assessments and regular physicals and weight collections to monitor health status. Injection site has been selected to minimize pain response to injections.
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).

   Alternatives to CFA have been evaluated including TiterMax and RIBI, however, they have not induced effective antibody responses in the context of proteins with highly homologous members in rabbit species. The investigator approves the use of analgesics and anesthetics, however, the IACUC determined that continuous pain control for this procedure without causing side effects by prolonged use of pain medications precluded the use of analgesics and anesthetics continuously throughout the study- therefore, drugs are used intermittently to minimize pain and distress but not continuously which leaves animals at category E.
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_____