

OCT 25 2016

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 (principal investigators and research staff), addresses, protocols, meeting notes (either in part or 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: 55-R-0127
2. Number 328 of animals used in this study.
3. Species (common name) Guinea pig 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, inappetence, respiratory signs, GI distress, vomiting, and diarrhea.

*Tetanus Potency - To quantitate the potency of Tetanus Immune Globulin (Human) by using neutralization methodology. Some of the animals will experience paralysis.*

5. Attach or include with the reason(s) for why anesthetics, analgesics and tranquilizers could not be used. (For federally mandated testing, see Item 6 below).

*This testing is mandated by Product License Testing requirements. Administration of anesthetic, analgesic or tranquilizer drugs would interfere with the outcome of the testing.*

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):

Agency FDA CFR 21 CFR 610.10