

## 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-0011

2. Number 220 of animals used in this study.

3. Species (common name) guinea pigs of animals used in the study.

4. Explain the procedure producing pain and/or distress.

Guinea pigs are passively sensitized by a single subconjunctival injection of antisera from guinea pigs that had been actively sensitized with ovalbumin. Eighteen to twenty-four hours later the eye is topically challenged with ovalbumin and the resulting allergic response is quantified. The guinea pigs are humanely euthanized at the completion of the study. The animals in Column E are positive controls and are expected to exhibit clinical signs of allergic response, including conjunctival congestion and redness, edema of the conjunctiva and eyelids, and discharge of tears or mucous.

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)

In this model of allergic conjunctivitis, sensitized guinea pigs are given a topical ocular challenge with antigen to induce an immediate hypersensitivity response typified by vascular leakage, swelling and edema, itching, vasodilation, and discharge of tears and mucous. These effects are transient and are usually reversed within 4-6 hours without therapeutic intervention or further antigen challenges. The animals are typically euthanized 24 hours after the antigen challenge. A positive control group is required in each experiment to determine the effects of therapeutic intervention by test compounds. The use of anti-inflammatory drugs, such as steroids or NSAIDs, to alleviate pain or distress would interfere with the allergic response in the positive control groups. The use of alternate opiate-based analgesics is also contraindicated because of the unknown effects of these drugs on the acute allergic response and their possible vasoconstrictive properties. Vasodilation of local blood vessels is a hallmark effect of acute allergic reactions. Interfering with this effect would negatively affect test results. Adding additional drugs to the system also increases the possibilities of unpredicted drug-drug interactions with critical test compounds.

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 N/A CFR N/A

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