

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: 16-R-001

2. Number 321 of animals used in this study.

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

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

Animals in this study will be used to study the pathogenic mechanisms of infectious agents with the goal of identifying new virulence factors and vaccine candidates to treat disease.

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 purpose of these studies is to identify potential vaccine candidates for an infectious agent that can cause clinical disease ranging from a self-limiting febrile illness to those associated with renal and/ or hepatic compromise. Since the course of the clinical disease is an immunopathologic process, the use of analgesics and anti-inflammatory drugs has the potential to alter the development of the disease and the ability to track its course.

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 _____

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1. Registration Number: 16-R-001

2. Number 2 of animals used in this study.

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

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

The opossum, which has a primitive uterus, is immunized to enhance isolation of follicular dendritic cells (FDC), which are genetically mapped for comparison with human FDC, to understand the evolutionary basis of the symbiotic relationship between higher order species and fetuses.

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 immunological reaction is needed to isolate the cells. Suppression of this reaction with analgesics and/or anti-inflammatory agents would negate the purpose of the immunization.

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Agency _____ CFR _____

NOV 30 2012

JAN 22 2013

October 1, 2011-September 30, 2012
Yale University 16-R-0001

Explanation for IACUC Approved Exceptions to USDA Regulations

Feeding

Nineteen *Macaca mulatta*, Category C, and fourteen *Macaca mulatta*, Category D, underwent reward-based food, but not fluid, regulation to optimize learning. Animals were given a reduced ration of standard monkey feed during the testing period of up to five days per week, but provided supplemental food and enrichment treats daily. Based on daily assessment, the total amount and variety of food consumed was sufficient to maintain the animals' health and well-being. Animals were returned to full feed when not on study.

Watering

Seven *Macaca mulatta*, Category C, and six *Macaca mulatta*, Category D, underwent reward-based water, but not food, regulation to optimize learning. Fluid intake, sufficient to maintain the animals' health and well-being, based on daily assessments, was accomplished by permitting the animals to earn fluid to satiety each day or an amount similar to the animal's average daily fluid intake during behavioral training and testing periods. Animals were returned to full water when not on study.

Single Housing

Fourteen *Macaca mulatta*, Category D were singly housed while participating in a self-administration drug study. When off-study the animals were returned to social housing.

Exemption to USDA Policy #14

One non-human primate (*Macaca mulatta*) is approved for the period from September 8, 2010 - September 30, 2012 for an exemption under 9CFR, Section 2.31(d)(1)(x)(C) to undergo multiple major operative procedures.