Georgia State University
Registration Number: 57-R-0012
Customer ID Number: 907

Explanation of and reason why pain and distress could not be relieved for **Category E Cotton Rats**:

1. Some of control (unvaccinated or mock control) animals that are infected with live RSV are expected to involve mild symptoms of illness (10-15% body weight loss) but they are expected to show normal activity in the behavior of eating and movement. The goal of this project is to assess the protective efficacy after RSV vaccination of cotton rat animals compared to that of unvaccinated control animals. Mild symptoms of illness will not be treatment with anesthetic, analgesic, or tranquilizing drugs. Treatment with anti-inflammatory analgesics that may interfere with the RSV disease progress in unvaccinated animals would affect the vaccine efficacy results of comparing the different vaccine groups compared to the unvaccinated group.
   Species: Cotton Rats
   Number of Animals Affected: 56

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Georgia State University adheres to the standards and regulations under the Act and requires that exceptions/exemptions to the standards and regulations be specified and explained by the principal investigator and approved by the IACUC. A summary of all such exceptions/exemptions can be seen below. In addition to identifying the IACUC-approved exceptions/exemptions, this summary includes a brief explanation of the exceptions/exemptions, as well as the species and number of animals affected.

Exception/Exemption

9 CFR AWA Part 3 (Subpart B) §3.31(a) (1)
"[Hamster] enclosures shall be sanitized at least once every 2 weeks..."
Cage accessories (wire bar top, food hopper, solid cage top, filter top) are changed out for all rodent species at least once a month congruent with the findings in the article entitled "Investigation of Appropriate Sanitization Frequency for Rodent Caging Accessories: Evidence Supporting Less-frequent Cleaning" as found in JAALAS, 45(6), 40-43, 2006; as well as in-house ATP testing performed between March 2019 and April 2019.
Species: Syrian Hamsters
Number of Animals Affected: 1540

Exception/Exemption

9 CFR AWA Part 3 (Subpart B) §3.33
"Animals housed in the same primary enclosure shall be maintained in compatible groups, …"
It is essential to be able to manipulate social housing conditions to study the effects of social experience on brain and behavior, so some Syrian Hamsters are singly housed. That would include experimental animals that were ordered and only ever singly housed, the Resident Aggressor (RA) colony, breeders (that may or may not have a litter with them), and any group housed animals that were eventually singly housed to become experimental animals, RAs, or breeders. Syrian Hamsters are solitary and territorial animals in the wild.
Species: Syrian Hamsters
Number of Animals Affected: 1400

9 CFR AWA (Subpart D) §3.81 (a) (1)
"(a) Social grouping. The environment enhancement plan must include specific provisions to address the social needs of nonhuman primates of species known to exist in social groups in nature. Such specific provisions must be in accordance with currently accepted professional standards, as cited in appropriate professional journals or reference guides, and as directed by the attending veterinarian. The plan may provide for the following exceptions:
(1) If a nonhuman primate exhibits vicious or overly aggressive behavior, or is debilitated as a result of age or other conditions (e.g., arthritis), it should be housed separately; '

Date	NHP ID	Reason for Exemption
	Hank	Hank is a 36-year-old male rhesus macaque, born 01/01/1983. His compatible conspecific was euthanized on 10/27/14 (cancer). Hank does not have another compatible conspecific. Due to Hank's advanced age and his arthritic condition, the AV (in conjunction with Clinical Laboratory Animal Veterinarian as well as the research staff) believe that introducing him to another macaque at this point in his life would not be in his best interest (would likely result in high anxiety and stress coupled with the concern that he could not adequately defend himself if attacked). Hank is permanently singly housed. He is housed in a room with 2 other rhesus macaques where he is able to have visual and auditory contact with these other rhesus monkeys and

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Explanation of and reason why pain and distress could not be relieved for **Category E Hamsters**:

1. One study will involve brief exposure to aggressive conspecifics to induce conditioned defeat. The purpose of the work is to determine how social defeat alters the brain and subsequent behavior. Giving a drug to alleviate the stress would alter the natural responses to this social stressor and thus defeat the purpose of the research. This behavior is naturally produced and of a brief duration.
2. One study will involve brief exposure to aggressive conspecifics and restraint stress. The purpose of the work is to determine how aggression and stress alters the brain and subsequent behavior. Giving a drug to alleviate the stress would alter the natural responses to this social stressor and thus defeat the purpose of the research. The researcher will study behavior that these animals naturally produce and that it is relatively mild and of a short duration.
   Species: Syrian Hamsters
   Number of Animals Affected: 928

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Explanation of and reason why pain and distress could not be relieved for **Category E Ferrets**:

1. In the ferret model, Influenza infection results in airway mucus production, lethargia, loss of bodyweight, increase of body temperature, and may even result in temporary limb paralyses. Providing pharmacologic agents for pain relieve will confound the model due to interference with the host immune response. Therefore, interventions need to be kept to an absolute minimum for a rigorous assessment of the benefit resulting from treatment with the drug candidates compared to vehicle-only treatment.
2. In the ferret model, CDV infection results in lethargia, loss of bodyweight, fever, vomiting, paralyses, diarrhea, rash and possibly seizures. Providing pharmacologic agents for pain relieve will confound the model due to interference with the host immune response (https://www.ncbi.nlm.nih.gov/pubmed/16764216). Although, buprenorphine has been shown to exhibit less immunosuppressive effects on host immune response in comparison to other opioids, it has still been shown to be capable of modulating the humoral immune response (https://www.ncbi.nlm.nih.gov/pubmed/29197801) and should not be used as an analgesic. Therefore, interventions need to be kept to an absolute minimum for a rigorous assessment of the benefit resulting from treatment with the drug candidates compared to vehicle-only treatment.

   Species: Domestic Ferret
   Number of Animals Affected: 91