

Category E Justifications FY 2021

Hamster H20-017

This protocol involves inoculation of hamsters with toxigenic *C. diff* from which unrelieved pain and suffering may be experienced. This is necessary in order to determine whether a PsV vaccine can protect hamsters from symptoms and death. Although every effort is made to identify and euthanize animals that become ill following *C. diff* infection, there are some animals that die naturally very suddenly (presumably because of systemic dissemination of *C. diff* toxin) without prior visible evidence of illness or distress, despite frequent observation. Animals will be monitored three times daily for 5 days following challenge, then daily until the end of the experiment two weeks after challenge. Control animals are expected to succumb within 48h of challenge. We expect our 5 day window of frequent observation to be sufficient to determine whether vaccinated animals will survive the challenge, or will have a delayed response. Daily observations thereafter are expected to be sufficient to monitor the health of the remaining animals. For animals that do develop severe disease symptoms, the endpoint criteria (Item T) will be followed, and animals meeting these criteria will be immediately euthanized with an overdose of euthanasia solution (Euthasol).