

Registration number 22-R-0030, December 1, 2011

A) Summary of exceptions to the regulations and standards

Site 1

Eighteen canines had exceptions from the exercise program for study related reasons but were housed in 100% of space requirements. The canines were either a part of (b) (4) and required complete collection of excreta (urine and feces). The studies occurred up to seven times and lasted less than 14 days. These exemptions were reviewed and approved by the IACUC.

Site 2

Forty-eight Rhesus Non-Human Primates (NHPs) had an exception related to cage change periods. The complete cleaning of the cage in a cage washer was delayed by up to 5 days for study related reasons; however daily standard husbandry cleaning was maintained the entire time period. For the study, the NHP cages (b) (4)

To perform a standard study and to collect data, the standard machine wash period was extended by 5 days and this occurred 1-4 times a year. Additionally, another 5 Rhesus were single housed for up to 22 days for EEG monitoring. The exception was reviewed and approved by the IACUC.

Thirty-nine Rhesus NHPs were granted exceptions by IACUC from the social housing standard in the environmental enrichment program for up to three week (b) (4). The study occurred only once or twice a year. All other aspects of the environment enrichment program were utilized. After the studies, the animals were placed back into social housing.

Nineteen Rhesus NHPs were granted exceptions by IACUC from the social housing standard in the environmental enrichment program. The NHPs were part of either (b) (4) and complete collection of excreta (urine and feces). The NHPs remained in the special collection cages until the (b) (4) of the excreta reaches normal levels. The NHP studies were usually of short duration and lasted only a few days. A couple of NHPs were single housed up to 14 days. Apart from the social housing,

the NHPs were included in the other aspects of the environmental enrichment program. After the study, they were returned to their normal social housing.

Thirty-six Rhesus NHPs were single housed with IACUC approval for sample collection (urine, stool, or bile) for up to 7 days or post dosing observation for 2 days or special food restrictions for up to 5 days. Apart from the social housing, the NHPs were included in the other aspects of the environmental enrichment program. After the study, they were returned to their normal social housing.

Thirty-two Rhesus NHPs were singly housed for evaluation of novel drugs to (b) (4)

Apart from the social housing, the NHPs were included in the other aspects of the environmental enrichment program. The exception was IACUC approved.

Eleven canines had exceptions from the exercise program for study related reasons but were housed in 100% of space requirements. The canines were either a (b) (4)

(b) (4) complete collection of excreta (urine and feces). The studies occurred up to seven times and lasted 4-36 days. These exemptions were reviewed and approved by the IACUC.

B) General Column 'E' Justification Statement

Site 1

One dog on an IACUC approved study to determine the (b) (4) (b) (4) developed acute terminal condition, although it had no clinical signs at its last observation. Due to lack of clinical signs veterinary medical intervention was not possible. Necropsy was not remarkable. The IACUC approved the study and reviewed the incident.

Site 2

Five hundred and forty-four hamsters developed acute terminal complications or were humanely euthanized in an IACUC-approved study to determine the (b) (4) the use of pain relief