

Study#1

1 Cynomolgus Macaque

Animals were inoculated with an infectious agent after treatment with vaccine or control therapy. This study is to demonstrate vaccine efficacy. Clinical signs must be observed without treatment in order to understand qualitative differences between treatment groups. The use of analgesics may have the secondary effect of masking clinical signs of infection that would prevent evaluation of disease severity such as the presence of fever. Other analgesics may interfere with clotting that could exacerbate disease.

The animals in this study were monitored at least twice each day and scored for 19 clinical signs of developing morbidity. Animals that receive a threshold score level are euthanized. Out of 27 cynomolgus macaques used for this study, 18 survived to the end of the study without developing any signs of infection sufficient to cause morbidity. Eight were assigned a threshold clinical score, were euthanized, and were counted as Category D animal use. One died without achieving a threshold clinical score and is, therefore, classified as category E animal use.

Study#2

1 Cynomolgus Macaque

Animals were inoculated with an infectious agent after treatment with vaccine or control therapy. This study is to demonstrate vaccine efficacy. Clinical signs must be observed without treatment in order to understand qualitative differences between treatment groups. The use of analgesics may have the secondary effect of masking clinical signs of infection that would prevent evaluation of disease severity such as the presence of fever. Other analgesics may interfere with clotting that could exacerbate disease.

The animals in this study were monitored at least twice each day and scored for 19 clinical signs of developing morbidity. Animals that receive a threshold score level are euthanized. Out of 26 cynomolgus macaques used for this study, 15 survived to the end of the study without developing any signs of infection sufficient to cause morbidity. Six were still alive at the end of the reporting period for this report. Four were assigned a threshold score level, were euthanized, and were counted as Category D animal use. One died without achieving a threshold clinical score and is, therefore, classified as category E animal use.

Study#3

1 Baboon

Animals were inoculated with an infectious agent. They did not receive treatment with vaccine or control therapy. This study is to establish an infectious dose in a non-human primate model. Clinical

2012 Category E Explanation

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signs must be observed without treatment in order to understand qualitative differences between treatment groups. The use of analgesics may have the secondary effect of masking clinical signs of infection that would prevent evaluation of disease severity such as the presence of fever.

The animals in this study were monitored at least twice each day and scored for 19 clinical signs of developing morbidity. Animals that receive a threshold score level are euthanized. Out of 3 baboons used for this study, 2 were assigned a threshold score level and were euthanized. One animal died without achieving a threshold clinical score and is, therefore, classified as category E animal use.

Study#4

1 Marmoset

Animals were inoculated with an infectious agent after treatment with vaccine or control therapy. This study is to demonstrate vaccine efficacy. Clinical signs must be observed without treatment in order to understand qualitative differences between treatment groups. The use of analgesics may have the secondary effect of masking clinical signs of infection that would prevent evaluation of disease severity such as the presence of fever. Other analgesics may interfere with clotting that could exacerbate disease.

The animals in this study were monitored at least twice each day and scored for 19 clinical signs of developing morbidity. Animals that receive a threshold score level are euthanized. Out of 6 marmosets used for this study, 5 were assigned a threshold score level, were euthanized, and were counted in Category D animal use. One animal died without achieving a threshold clinical score and is, therefore, classified as category E animal use.