According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0579-0036. The time required to complete this information collection is estimated to average .5 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

OMB APPROVED
0579-0036

Interagency Report Control No. 0180-DOA-AN

Fiscal year: FY21

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

Annual Report of Research Facility
Column E Explanation

(TYPE OR PRINT)

This information is required by law (7 U.S.C. 2143 and 9 C.F.R. §2.36). Failure to report according to the regulations can result in an order to cease and desist.

1. REGISTRATION NUMBER

14-R-0017

2. Research Facility Headquarters address

700 Albany Street
Boston, MA 02118

3. Number of animals used in the study.

748

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

Hamsters

5. Explain the procedure producing pain and distress.

Coronavirus challenge for evaluation of therapeutic efficacy
Coronavirus challenge for evaluation of vaccine efficacy
Coronavirus challenge for virulence testing

The IACUC approved this Column E activity.

6. Provide the scientific justification for not providing the appropriate anesthetics, analgesics, or tranquilizing drugs during procedures where the animal experienced accompanying pain or distress greater than momentary or slight.

For the disease models no analgesics will be used since analgesics have the secondary effect of masking clinical signs of infection preventing evaluation of disease severity and therefore timely intervention. In addition, analgesics may exacerbate clotting deficiencies in diseases that already impact clotting. The euthanasia criteria were developed to help minimize pain or distress while still allowing sufficient time to collect data to validate a treatment.

7. 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

Obtained by Rise for Animals.
Uploaded to Animal Research Laboratory Overview (ARLO) on 07/22/2022

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1. REGISTRATION NUMBER

14-R-0017

2. Research Facility Headquarters address

700 Albany Street
Boston, MA 02118

3. Number of animals used in the study.

16

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

Cynomolgus monkey

5. Explain the procedure producing pain and distress.

SARS CoV-2 inoculation for therapeutic evaluation studies (cynomolgus)
SARS CoV-2 inoculation for vaccine evaluation studies (cynomolgus)
SARS CoV-2 inoculation following infection with a related coronavirus (cynomolgus)

This Column E activity was approved by the IACUC.

6. Provide the scientific justification for not providing the appropriate anesthetics, analgesics, or tranquilizing drugs during procedures where the animal experienced accompanying pain or distress greater than momentary or slight.

Animals cannot be treated as any treatment would interfere with the outcome of the study rendering the study data uninterpretable. NSAIDS cannot be used because these drugs inhibit prostaglandin and leukotriene synthesis, and stabilize lysosomal membranes impacting cytokine activity. These affected systems are target systems that are to be evaluated in these studies. Opiates are not indicated because the pain experienced consists of a non-specific malaise that may not be improved by opiates. Further, opiates may increase mortality due to interference with cardiovascular and respiratory systems. Rather, pain and distress are minimized by using a score sheet to determine when an animal should be euthanized.

7. 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

Obtained by Rise for Animals.
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1. REGISTRATION NUMBER

14-R-0017

2. Research Facility Headquarters address

700 Albany Street
Boston, MA 02118

3. Number of animals used in the study.

104 (61 rhesus, 43 cynomolgus)

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

Rhesus monkey, cynomolgus monkey

5. Explain the procedure producing pain and distress.

Filovirus challenge for confirmation of virulence studies (rhesus)
Filovirus challenge for natural history studies (rhesus)
Filovirus challenge for therapeutic evaluation (rhesus)
Filovirus challenge for vaccine evaluation (cynomolgus)
Filovirus challenge via the intranasal route (cynomolgus)

This Column E activity was approved by the IACUC.

6. Provide the scientific justification for not providing the appropriate anesthetics, analgesics, or tranquilizing drugs during procedures where the animal experienced accompanying pain or distress greater than momentary or slight.

Animals cannot be treated as any treatment would interfere with the outcome of the study rendering the study data uninterpretable. NSAIDS cannot be used because these drugs inhibit prostaglandin and leukotriene synthesis, and stabilize lysosomal membranes impacting cytokine activity. These affected systems are target systems that are to be evaluated in these studies. Opiates are not indicated because the pain experienced consists of a non-specific malaise that may not be improved by opiates. Further, opiates may increase mortality due to interference with cardiovascular and respiratory systems. Rather, pain and distress are minimized by using a score sheet to determine when an animal should be euthanized.

7. 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

Obtained by Rise for Animals.
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