Optional Column E Explanation Form

27 NOV 2017

1. **Registration Number:** 51-F-021 / 728

2. **Number** 454 **of animals used in this study.**

3. **Species (common name)** Guinea Pigs **of animals used in this study.**

4. **Explain the procedure producing pain and/or distress.**

   Guinea pigs used in research at the United States Army Medical Research Institute of Infectious Diseases and reported in Column E experienced pain and/or distress due to one of the following circumstances:

   a. Use on a pathogenesis study in which they were infected by parenteral injection or aerosol exposure to a CDC Select Agent or other high hazard agent (bacterial or viral infectious agents) and allowed to develop the disease.
   b. Use on a vaccine study in which they were vaccinated against a CDC Select Agent or other high hazard agent (bacterial or viral infectious agents or biological toxins) and subsequently exposed by parenteral injection or aerosol exposure to the infectious agent or toxin. Animals that were used in control groups experienced pain and/or distress when they developed the disease as did any animals in which the vaccine was not completely efficacious in preventing the infection or intoxication.
   c. Use on a therapeutic study in which animals were treated with a drug either before or after exposure to a CDC Select agent or other high hazard agent (bacterial or viral infectious agents) by parenteral injection or aerosol exposure. Animals that were used in control groups experienced pain and/or distress when they developed the disease as did any animals in which the drug was not completely efficacious in preventing or treating the infection.

5. **Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see question 6 below)**

The retardation or relief of clinical signs with pain relieving or anesthetic drugs result in inaccurate experimental data because these drugs interfere with certain clinical and immunological responses to biological agents by the test animal, and subsequent analysis of those responses. All studies that result in unalleviated pain or distress to experimental animals require scientific justification, in writing, explaining in detail, why the use of pain relieving drugs is not appropriate and how it would interfere with the scientific goals of the study. Each of these protocols is evaluated on a case by case basis by the IACUC.

6. **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 N/A **CFR** N/A

Optional Column E Explanation Form

27 NOV 2017

1. **Registration Number:** 51-F-021 / 728

2. **Number** 256 **of animals used in this study.**

3. **Species (common name)** Hamsters **of animals used in this study.**

4. **Explain the procedure producing pain and/or distress.**

   Hamsters used in research at the United States Army Medical Research Institute of Infectious Diseases and reported in Column E experienced pain and/or distress due to one of the following circumstances:

   a. Use on a pathogenesis study in which they were infected by parenteral injection or aerosol exposure to a CDC Select Agent or other high hazard agent (bacterial or viral infectious agents) and allowed to develop the disease.
   b. Use on a vaccine study in which they were vaccinated against a CDC Select Agent or other high hazard agent (bacterial or viral infectious agents) and subsequently exposed by parenteral injection or aerosol exposure to the infectious agent. Animals that were used in control groups experienced pain and/or distress when they developed the disease as did any animals in which the vaccine was not completely efficacious in preventing the infection.
   c. Use on a therapeutic study in which animals were treated with a drug either before or after exposure to a CDC Select agent or other high hazard agent (bacterial or viral infectious agents) by parenteral injection or aerosol exposure. Animals that were used in control groups experienced pain and/or distress when they developed the disease as did any animals in which the drug was not completely efficacious in preventing or treating the infection.

5. **Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see question 6 below)**

The retardation or relief of clinical signs with pain relieving or anesthetic drugs result in inaccurate experimental data because these drugs interfere with certain clinical and immunological responses to biological agents by the test animal, and subsequent analysis of those responses. All studies that result in unalleviated pain or distress to experimental animals require scientific justification, in writing, explaining in detail, why the use of pain relieving drugs is not appropriate and how it would interfere with the scientific goals of the study. Each of these protocols is evaluated on a case by case basis by the IACUC.

6. **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 N/A **CFR** N/A

Optional Column E Explanation Form

1. **Registration Number:** 51-F-021 / 728 27 NOV 2017

2. **Number** 190 **of animals used in this study.**

1. **Species (common name)** Non-human Primates **of animals used in this study.**

2. **Explain the procedure producing pain and/or distress.**

Nonhuman primates used in research at the United States Army Medical Research Institute of Infectious Diseases and reported in Column E experienced pain and/or distress due to one of the following circumstances:

a. Use on a pathogenesis study in which they were infected by parenteral injection or aerosol exposure to a CDC Select Agent or other high hazard agent (bacterial or viral infectious agents) and allowed to develop the disease.
b. Use on a vaccine study in which they were vaccinated against a CDC Select Agent or other high hazard agent (bacterial or viral infectious agents or biological toxins) and subsequently exposed by parenteral injection or aerosol exposure to the infectious agent or toxin. Animals that were used in control groups experienced pain and/or distress when they developed the disease as did any animals in which the vaccine was not completely efficacious in preventing the infection or intoxication.
c. Use on a therapeutic study in which animals were treated with a drug either before or after exposure to a CDC Select agent or other high hazard agent (bacterial or viral infectious agents) by parenteral injection or aerosol exposure. Animals that were used in control groups experienced pain and/or distress when they developed the disease as did any animals in which the drug was not completely efficacious in preventing or treating the infection.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see question 6 below)

The retardation or relief of clinical signs with pain relieving or anesthetic drugs result in inaccurate experimental data because these drugs interfere with certain clinical and immunological responses to biological agents by the test animal, and subsequent analysis of those responses. All studies that result in unalleviated pain or distress to experimental animals require scientific justification, in writing, explaining in detail, why the use of pain relieving drugs is not appropriate and how it would interfere with the scientific goals of the study. Each of these protocols is evaluated on a case by case basis by the IACUC.

6. 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 N/A **CFR** N/A

Optional Column E Explanation Form

1. **Registration Number:** 51-F-021 / 728 27 NOV 2017

2. **Number** 18 **of animals used in this study.**

5. **Species (common name)** Ferrets **of animals used in this study.**

6. **Explain the procedure producing pain and/or distress.**

Rabbits used in research at the United States Army Medical Research Institute of Infectious Diseases and reported in Column E experienced pain and/or distress due to one of the following circumstances:

d. Use on a pathogenesis study in which they were infected by parenteral injection or aerosol exposure to a CDC Select Agent or other high hazard agent (bacterial or viral infectious agents) and allowed to develop the disease.
e. Use on a vaccine study in which they were vaccinated against a CDC Select Agent or other high hazard agent (bacterial or viral infectious agents or biological toxins) Use and subsequently exposed by parenteral injection or aerosol exposure to the infectious agent or toxin. Animals that were used in control groups experienced pain and/or distress when they developed the disease as did any animals in which the vaccine was not completely efficacious in preventing the infection or intoxication.
f. Use on a therapeutic study in which animals were treated with a drug either before or after exposure to a CDC Select agent or other high hazard agent (bacterial or viral infectious agents) by parenteral injection or aerosol exposure. Animals that were used in control groups experienced pain and/or distress when they developed the disease as did any animals in which the drug was not completely efficacious in preventing or treating the infection.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see question 6 below)

The retardation or relief of clinical signs with pain relieving or anesthetic drugs result in inaccurate experimental data because these drugs interfere with certain clinical and immunological responses to biological agents by the test animal, and subsequent analysis of those responses. All studies that result in unalleviated pain or distress to experimental animals require scientific justification, in writing, explaining in detail, why the use of pain relieving drugs is not appropriate and how it would interfere with the scientific goals of the study. Each of these protocols is evaluated on a case by case basis by the IACUC.

6. 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 N/A **CFR** N/A