Column E Explanations

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1. Registration Number: 51-R-0018

2. Number _____22_____ of animals categorized as column E 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.

   Animals are exposed to organophosphorus (OP) compounds to induce signs of OP toxicity.

5. Attach or include the reason(s) for why anesthetics, analgesics and tranquillizers could not be used. (For Federally mandated testing, see Item 6 below).

   The purpose of these refined studies are to develop FDA approved medical countermeasures against OP toxicity (acute and delayed effects) such as might occur in a chemical warfare situation or terrorist attack. The administration of OP nerve agents may cause distress. The testing of treatments requires OP toxicity to be present in order to evaluate the effectiveness of the treatment. While anticonvulsants and sedatives are used, there is still some possibility that the animal will experience unrelieved distress relative to the effects of OP intoxication. Animals are closely monitored and animals showing any life threatening signs of OP toxicity and/or respiratory distress are immediately euthanized.

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: FDA, CFR Title 21, § 314 & 601

22 NOV 2017

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1. Registration Number: 51-R-0018

2. Number _____28_____ of animals categorized as column E used in this study.

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

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

Subsequent to testing efficacy of vaccine candidates in mice, hamsters (the gold standard for Clostridium difficile infection (CDI)) will be used to evaluate vaccine candidates in an effort to develop human therapies for the leading cause of nosocomial antibiotic-associated diarrhea and the etiologic agent of pseudomembranous colitis.

5. Attach or include the reason(s) for why anesthetics, analgesics and tranquillizers could not be used. (For Federally mandated testing, see Item 6 below).

This protocol will evaluate the efficacy of immune based interventions (vaccine and antibody therapies) against CDI. CDI in hamsters is fulminant and almost always rapidly fatal unless treated. Only new therapeutics that show excellent results in mice will be tested in hamsters. Analgesics cannot be used in this work because they mask clinical signs of disease and alter behavior. Clinical signs such as lethargy, depression and hunched posture are critical for determining severity of disease and alternative endpoints and it will satisfy the need for pre-clinical safety and efficacy data prior to conducting clinical trials in humans.

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: FDA, CFR 21, § 314 & 601

22 NOV 2017

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1. Registration Number: 51-R-0018

2. Number _____31_____ of animals categorized as column E used in this study.

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

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

   Animals undergo survival surgery (cardiac arrest and various methods of resuscitation). Animals are maintained under general anesthesia and provided morphine for pain control as part of a standard intensive care protocol. At approximately 22 hours post-resuscitation animals are weaned from propofol and controlled ventilation. At 22.5 hours, morphine is reversed with naloxone and animals undergo neurologic deficit scoring (NDS). Following NDS, animals are re-anesthetized for euthanasia and harvest of tissues / organs.

5. Attach or include the reason(s) for why anesthetics, analgesics and tranquillizers could not be used. (For Federally mandated testing, see Item 6 below).

   Animals are exposed to untreated pain for approximately three minutes during neurologic deficit scoring. This is unavoidable in light of the need to assess an accurate measurement of the clinical, neurologic outcome in an attempt to develop a human clinical trial for therapy of brain injury following resuscitation from cardiac arrest.

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: CFR

22 NOV 2017

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1. Registration Number: 51-R-0018

2. Number _____5_____ of animals categorized as column E used in this study.

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

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

Animals in this study will undergo an invasive thoracic surgery. Given the nature of sheep behavior, animals will be housed in stanchions to mitigate the risks of self-induced post-operative complications.

5. Attach or include the reason(s) for why anesthetics, analgesics and tranquillizers could not be used. (For Federally mandated testing, see Item 6 below).

Although animals will be treated with appropriate analgesics, sedatives and anesthetics, it is possible animals may not express species-specific behavior associated the housing system used to prevent possible self-induced post-operative complications.

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: NA

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1. Registration Number: 51-R-0018

2. Number _____26_____ of animals categorized as column E used in this study.

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

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

   The objective of this research is to develop an animal model of acute radiation sickness across the dose range to induce the hematopoietic subsyndrome of acute radiation syndrome to assess the relationship between thrombocytopenia, coagulopathy, and associated vascular etiologies.

5. Attach or include the reason(s) for why anesthetics, analgesics and tranquillizers could not be used. (For Federally mandated testing, see Item 6 below).

   While analgesics, anesthetics and/or sedatives will be used to relieve pain and/or distress, there is still some possibility that the animal will experience unrelieved pain and/or distress relative to the effects of high dose irradiation.

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: FDA, CFR Title 21, § 314 & 601

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1. Registration Number: 51-R-0018

2. Number _____24_____ of animals categorized as column E used in this study.

3. Species (common name) _Non-Human Primate (Rhesus) of animals used in this study.

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

Animals will be used to develop a biodosimeter, testing blood markers based on the delivered radiation dose below the threshold that causes ill-health.

5. Attach or include the reason(s) for why anesthetics, analgesics and tranquillizers could not be used. (For Federally mandated testing, see Item 6 below).

Although the radiation doses utilized in this protocol are below the threshold to cause ill-health due to organ damage, it is possible some animals may still experience unrelieved pain and/or distress despite the administration of analgesics for pain.

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: FDA, CFR Title 21, § 314 & 601

APHIS Form 7023 Site Addendum for FY:

Registration Number: 51-R-0018
Customer ID Number: 89

Facility Business Address Information:

University Of Maryland Baltimore
10 S. Pine St. Rm G-100, Mstf Bldg.
Baltimore, MD 21201

Telephone: (410-706-3540

Facilities Site(s) Address Information:

Site Code(s):

29 NOV 2018

Column E Explanations

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1. Registration Number: 51-R-0018

2. Number _____30_____ of animals categorized as column E 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 will develop severe, fulminant Clostridium difficile infection (CDI).

5. Attach or include the reason(s) for why anesthetics, analgesics and tranquillizers could not be used. (For Federally mandated testing, see Item 6 below).

   This protocol will evaluate the efficacy of immune based interventions (vaccine and antibody therapies) against CDI. CDI in hamsters is fulminant and almost always rapidly fatal unless treated. Only new therapeutics that show excellent results in mice will be tested in hamsters. Analgesics cannot be used in this work because they mask clinical signs of disease and alter behavior. Clinical signs such as lethargy, depression and hunched posture are critical for determining severity of disease and alternative endpoints.

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: FDA Animal Rule CFR Title 21, Parts 314 & 601

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1. Registration Number: 51-R-0018

2. Number _____79_____ of animals categorized as column E used in this study.

3. Species (common name) __Guinea pig_____ of animals used in this study.

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

Animals injected with a supra-lethal dose of chlorpyrifos will receive therapeutic intervention to curtail the CPF-induced acute toxicity.

5. Attach or include the reason(s) for why anesthetics, analgesics and tranquillizers could not be used. (For Federally mandated testing, see Item 6 below).

Following the insecticide exposure, the animals will be treated with atropine. However, despite this treatment, some of the guinea pigs may still experience acute signs of toxicity.

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):

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1. Registration Number: 51-R-0018

2. Number _____8_____ of animals categorized as column E used in this study.

3. Species (common name) __Guinea pig_____ of animals used in this study.

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

Guinea pigs will be immunized with Shigella vaccines that will be tested in humans, and they will be challenged with virulent S. flexneri using both the Sereny test and rectocolitis infection to determine vaccine efficacy (protection).

5. Attach or include the reason(s) for why anesthetics, analgesics and tranquillizers could not be used. (For Federally mandated testing, see Item 6 below).

Buprenorphine is administered.

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):

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1. Registration Number: 51-R-0018

2. Number _____60_____ of animals categorized as column E used in this study.

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

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

Animals may experience unrelieved pain and/or distress as a result of acute radiation sickness.

5. Attach or include the reason(s) for why anesthetics, analgesics and tranquillizers could not be used. (For Federally mandated testing, see Item 6 below).

Buprenorphine is administered starting at the time of irradiation and thereafter up to 3x per day if pain is suspected throughout the 45-day follow-up.

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):

FDA Animal Rule CFR Title 21, Parts 314.600 through 314.650 - drugs
or 601.90 through 601.95 -biological products

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1. Registration Number: 51-R-0018

2. Number _____44_____ of animals categorized as column E used in this study.

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

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

Animals may experience unrelieved pain and/or distress as a result of acute radiation sickness.

5. Attach or include the reason(s) for why anesthetics, analgesics and tranquillizers could not be used. (For Federally mandated testing, see Item 6 below).

Buprenorphine is administered starting at the time of irradiation and thereafter up to 2x per day if pain is suspected throughout the follow-up.

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):

FDA Animal Rule CFR Title 21, Parts 314.600 through 314.650 - drugs
or 601.90 through 601.95 -biological products

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1. Registration Number: 51-R-0018

2. Number _____15_____ of animals categorized as column E used in this study.

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

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

Animals may experience gate abnormality after rotator cuff injury.

5. Attach or include the reason(s) for why anesthetics, analgesics and tranquillizers could not be used. (For Federally mandated testing, see Item 6 below).

Buprenorphine is administered.

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):

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1. Registration Number: 51-R-0018

2. Number _____11_____ of animals categorized as column E used in this study.

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

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

Animals will be implanted with artificial lung pump. Given the nature of this surgical approach, animals in this study are at risk for dislodgement of cannulae, incisional dehiscence, and pneumothorax and/or hemothorax during their recovery period. For these reasons, animals in this study will be restrained in a modified metabolic stanchion for up to 10 days post-operatively, in order to minimize post-operative complications.

5. Attach or include the reason(s) for why anesthetics, analgesics and tranquillizers could not be used. (For Federally mandated testing, see Item 6 below).

Flunixin Meglumine and fentanyl (patch) is administered

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):

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1. Registration Number: 51-R-0018

2. Number _____10_____ of animals categorized as column E used in this study.

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

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

Animals may experience unrelieved pain and/or distress as a result of acute radiation sickness.

5. Attach or include the reason(s) for why anesthetics, analgesics and tranquillizers could not be used. (For Federally mandated testing, see Item 6 below).

Analgesics are administered as soon as pain and distress is detected.

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):