Column E Explanations

This form is intended as an aid to complete the Column E explanation. It is not an official form and its use is voluntary. Annual Reports and explanations should NOT include PI information such as names (principal investigator and research staff), addresses, protocols, meeting notes (either in part or in full), the animals room numbers, grant information, veterinary care programs, and the like. A Column E explanation must be written so as to be understood by lay persons as well as scientist.

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):