"Column E" Explanation

This form is intended as an aid to completing the Column E explanation. It is not an official form and its use is voluntary. Names, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation. *A Column E explanation must be written so as to be understood by lay persons as well as scientists.*

1. Registration Number: **74-R-0012**

2. Number of animals used in this study: **12**

3. Species (common name) of animals used in the study: **New Zealand White Rabbits**

4. What is the purpose of this study?
   The purpose of this study is three fold:
   (1) Allow the ticks to feed on the rabbits for maintenance of the tick colony
   (2) Generate and isolate tick tissue for vaccine development
   (3) Test anti-tick vaccines for efficacy

5. Describe what pain and/or distress occurred; and explain the procedure producing pain and/or distress:
   During the tick infestation, we place an Elizabethan collar to prevent the rabbits from scratching off the tick containment apparatus. If ticks repeatedly infest rabbits, the rabbits can develop an allergy to tick saliva proteins. This "allergy" can cause skin irritation and itching. We limit the formation of these reactions by limiting the tick feeding periods to two times per animal. However, even with limiting the feeding periods we may still have some skin irritation and itching.

6. 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:
   The central goal of the research is to understand how ticks evade the host defense mechanism which allows the ticks to feed. By determining these mechanisms we will be able to find important tick proteins that can be used to develop anti-tick vaccines. Artificial feeding of the ticks would not be a suitable alternative since we need an intact host immune system to determine the role of the tick proteins. The potential pain and/ or distress associated with this study is due to the rabbits developing an immunological (allergic) response to the tick proteins which results in skin irritation and itching. This normally occurs after repeated tick feeding episodes. We attempt to minimize these reactions by limiting the tick feeding to two periods. Although this process eliminates most of the allergy development, we can't guarantee it will eliminate all of the reactions to the tick proteins. We could prevent animals from developing resistance to tick feeding by injecting them with immune-suppressants; however this would compromise our results since we are trying to elucidate how the tick proteins affect the host immune system.

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): **(Not Applicable)**

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1. Registration Number: **74-R-0012**

2. Number of animals used in this study: **24**

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

4. What is the purpose of this study?
Coxiella burnetii, the etiologic agent of Q fever, is a highly transmissible pathogen with significant risk for use as a biological agent of terrorism. Currently, there are no vaccines available for widespread use in the US, and those that are available in other countries may cause severe adverse reactions and require time-consuming testing prior to vaccination. A new vaccine is therefore needed that is both effective in preventing Q fever and safe for routine use. Recombinant proteins and soluble fractions from C. burnetii strain will be produced as vaccine candidates and used to immunize animals. Animals will subsequently be challenged with virulent C. burnetii and the safety and protectiveness of vaccine candidates will be determined.

5. Describe what pain and/or distress occurred; and explain the procedure producing pain and/or distress:
Guinea pigs may develop clinical disease if the candidate vaccines do not provide protection from Q fever challenge. They will be monitored daily after infection for fever. At the first signs of fever the animals will be classified as "ill" and will then have respiratory rates and weight taken on a daily basis. Animals will be removed from the study and humanely euthanized, if they develop significant clinical signs (ruffled fur, decrease >15% of their body weight, and/or developed labored breathing.

6. 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:
A challenge by the infectious organism is necessary to determine the effectiveness of the vaccine candidates. Simply checking antibody titers does not necessarily confer protection.

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): **(Not Applicable)**

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1. Registration Number: **74-R-0012**

2. Number of animals used in this study:
   8 Raccoons
   17 Opossums
   100 Wild Capture Mice
   36 Wild Capture Rats

3. Species (common name) of animals used in the study:
   Raccoons, Opossums, Wild Capture Mice and Rats

4. What is the purpose of this study?
   There is a critical need to determine the ecological factors promoting the differential incidence of lymes disease in the Southern US not just in the Northeast and Midwest of the US as the agent, vector and mammalian hosts are present in all geographic regions. In addition, there is limited information on the genetic diversity of *Ixodes scapularis* the tick vector for this disease, and on the role of that the vector's genetic diversity has in explaining the risk of contracting lymes disease.

5. Describe what pain and/or distress occurred; and explain the procedure producing pain and/or distress:
   Since this study involves the capture and caging of wild animals, it is thought there may be distress due to captivity. Hide boxes will be provided to allow the animals to find a place to hide and help cope with stress. No painful procedures will be performed on these animals. These animals exhibited normal appetite and attitude during the one week of captivity.

6. 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:
   Tranquilization of the animals to relieve the potential stress of captivity may be deleterious and alter the animal's normal behavior, appetite and water consumption, due to extra handling of the animals.

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): **(Not Applicable)**