Column E Explanation

1. Registration Number: 52-R-0012

2. Number of animals categorized as column E used in this study. 96

3. Species animals used in this study, pigs.

4. Explain the procedure producing pain and/or distress. Explanations should include a brief description of the procedure, but also explain what the animal's experience, examples of which may include, but are not limited to: Neurological signs, seizures, tremors, paralysis, lethargy, inappetance, respiratory signs, GI distress, vomiting, and diarrhea.

   Piglets infected with the virus are expected to experience watery diarrhea, and occasional vomiting particularly in unvaccinated groups which may lead to transient dehydration. The infection in pigs is self-limiting and diarrhea stops within 3-5 days.

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

   Due to the importance of observing diarrhea, which is a key marker for the studies of the vaccine protective efficacy in this protocol, the piglets will not be administered any antibiotics, anti-inflammatories or electrolytes in order to alleviate the symptoms of virus infection. In particular, antibiotics are not indicated for treatment of the pigs because some of the research involves a microbiota or probiotic component, in which case antibiotic treatment would invalidate results. Hence, the normal course of infection in piglets of both unvaccinated and vaccinated groups have to be allowed in this study in order to evaluate the protection efficacy of the experimental vaccines tested against virus diarrhea.

6. What, if any, federal regulation requires 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): If the requirement is per a guidance document, such as an Agency notice or harmonization guideline, please provide specific sufficient information to identify the cited document.

   Agency _____   CFR