According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0579-0036. The time required to complete this information collection is estimated to average .5 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

OMB APPROVED 0579-0036 Interagency Report Control No. 0180-DOA-AN Fiscal year: 2020

UNITED STATES DEPARTMENT OF AGRICULTURE ANIMAL AND PLANT HEALTH INSPECTION SERVICE

Column E Explanation (TYPE OR PRINT)		
This information is required by law (7 U.S.C. 2143 and 9 C.F.R. §2.36). Failure to report according to the regulations can result in an order to cease and desist.		
1. REGISTRATION NUMBER	2. Research Facility Headquarters address	
52-R-0011	P. O. Box 40	f Virginia, Office of VP for Research 00301 lle, VA 22904
3. Number of animals used in the study.	4. Species (common name) of animals used in the study.	
2	swi	ne
5. Explain the procedure producing pain and distress.		
This study is mapping the pain pathway of swine from the periphery to the reticular system through the spinal cord and midbrain. Once specific pain pathways are identified, they are lesioned using focused ultrasound, which is a non-invasive manner to do some brain procedures. This is being tested as a method to interfere with chronic pain perception.		
6. Provide the scientific justification for not providing the appropriate anesthetics, analgesics,		
or tranquilizing drugs during procedures where the animal experienced accompanying pain or distress greater than momentary or slight.		
Since the intent of the study is to map pain pathways in swine, analgesics and non-steroidal anti-inflammatory drugs directly interfere with the mapping procedure.		
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):		
None Agency		CFR
Agonoy		

Column E Explanation

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 PII information such as names (principle investigators and research staff), addresses, protocols, meeting notes (either in part of 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 person as well as scientists.

- 1. Registration Number: 52-R-0011
- 2. Number of animals categorized as column E used in this study. 2
- 3. Species (common name) of animals used in this study. Swine
- 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.

This study is mapping the pain pathway of swine from the periphery to the reticular system through the spinal cord and midbrain. Once specific pain pathways are identified, they are lesioned using focused ultrasound, which is a non-invasive manner to do some brain procedures. This is being tested as a method to interfere with chronic pain perception.

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).

Since the intent of the study is to map pain pathways in swine, analgesics and non-steroidal antiinflammatory drugs directly interfere with the mapping procedure.

6. What, if any, federal regulation 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): 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.

None

- 1. Registration Number: 52-R-0011
- 2. Number of animals categorized as column E used in this study. 124
- 3. Species (common name) of animals used in this study. Rabbit
- 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.

5. Explain the procedure producing pain and distress.

Neonatal rabbits have Shigella flexneri instilled intra-rectal while under anesthesia. For the next week they develop dysentery which is studied but not treated. The Shigella is genetically manipulated to determine which of its genes are involved in the progression and severity of dysentery.

6. Provide the scientific justification for not providing the appropriate anesthetics, analgesics, or tranquilizing drugs during procedures where the animal experienced accompanying pain or distress greater than momentary or slight.

Analgesics in the opiate category change bowel motility and therefore cannot be used to study the ensuing dysentery in the bunnies. Similarly, non-steroidal anti-inflammatory drugs alter the course of the dysentery which is being studied. Nursing care support is provided to facilitate hydration and provision of dietary calories during the dysentery that progresses over a seven day period after which the rabbits are humanely euthanized with Euthasol.

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):

None