OMB APPROVED
0579-0036

Interagency Report Control No. 0180-DOA-AN

Fiscal year: 2021

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

Annual Report of Research Facility
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
31-R-0014/216	Ohio State University 1960 Kenny Rd. Columbus, OH 43210
3. Number of animals used in the study:	**4. Species (common name) of animals used inthe study.**
1	Pig

5. Explain the procedure producing pain and distress.

This study used a spinal muscular atrophy (SMA) pig model that exhibited symptoms of progressive limb paresis in order to test gene therapy efficacy. The limb weakness reduced ability to ambulate normally may have caused distress.

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

In order to determine if gene therapy is successful, the progression of muscle weakness is monitored over time in affected animals using clinical observations and physiologic function monitoring. Animals which exhibit rear limb weakness or paralysis are not be removed from the study if there is no significant progression to the forelimbs. Supportive care was provided to animals exhibiting clinical signs to ensure the distress is minimized as much as possible. A lack of disease progression indicates the gene therapy is effective, and further characterization of the duration of the effectiveness is essential to understanding of this treatment and its potential application to human patients.

If the front limbs become weak or there is a clear indication of denervation according to the electromyography, then the treatment will be deemed ineffective, and the animal will be removed from the study and humanely euthanized.

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):

Agency: N/A	**CFR:** N/A