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Fiscal year: 2024

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

52-R-0011

2. Research Facility Headquarters address

University of Virginia, Office of Vice President for Research
P.O. Box 400301
Charlottesville, VA 22904

3. Number of animals used in the study.

2

4. Species (common name) of animals used in the study.

Pigs

5. Explain the procedure producing pain and distress.

This study investigates neurobiological processes that occur in the transition from acute to chronic neuropathic pain. The pathophysiological mechanisms of neuropathic pain are not as well defined as for nociceptive pain (initial pain perception of body damage), and therefore neuropathic pain is more difficult to treat. The goal is to record and monitor electrical signals within various deep and superficial brain nuclei in order to better understand neuropathic pain transduction (how pain is encoded in electrical impulses) and transmission. The specific procedure producing pain and distress is the cortical/subcortical monitoring electrode implantation and sciatic nerve dissection (combined surgery under general anesthesia). The primary aim of the study is to improve the understanding of these neuropathic pain pathways using a swine model in order to better treat humans who suffer from chronic neuropathic pain.

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.

Animals receive appropriate anesthetic agents during the electrode implantation and nerve constriction surgeries. They also receive appropriate post-operative analgesic medications to treat the expected pain from skin incision and tissue dissection. As this procedure requires the development of neuropathic pain from sciatic nerve constriction, animals do develop hyperalgesia and allodynia in the affected limb 1-2 weeks after the nerve constriction surgery. Animals are not in distress for the majority of the experiment. This has been confirmed by prior published studies of similar animal models in pigs and sheep. The study is terminated early if significant signs of distress are noted. The experiment does not extend beyond eight weeks after nerve constriction injury in order to minimize animal discomfort. Neuropathic pain must be initiated via sciatic nerve constriction in order to study the electrophysiologic changes in various brain nuclei in the setting of neuropathic pain. This gives researchers more information to guide treatments, i.e., ablative methods (focused ultrasound) and reduce neuropathic pain by severing pain pathways. Animals cannot be treated or minimize neuropathic pain in this study as it prevents accurate recording of data. By treating neuropathic pain, researchers will not be able to record changes in electrophysiologic activity in various brain nuclei during the evolution of acute to chronic neuropathic pain, and therefore not be able to map pain pathways (post- operative pain as appropriate).

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

INSTRUCTIONS FOR COMPLETION OF APHIS FORM 7023B

(Refer to U.S.C. 7 Section 7A and 9 C.F.R. § 2.36)

Submit a separate form per species per study

ITEM 1 - Enter registration number as assigned to the Research Facility by United States Department of Agriculture (USDA).

ITEM 2 - Enter the complete name and address of the Headquarters Research Facility as registered with USDA. If the name or business address has changed, notify the Fort Collins, CO office in writing as soon as possible. Correcting the information on your annual report packet is not sufficient.

ITEM 3 - Indicate the numbers of animals used in the Column E portion of the study.

ITEM 4 - Indicate the common names of the animals

ITEM 5 - Summarize the procedure for which the animals did not receive appropriate anesthetics, analgesics or tranquilizing drugs to relieve accompanying pain or distress. DO NOT provide specific information such as study title, protocol number, or name of the Principal Investigator.

ITEM 6 - The scientific justification is to address the adverse effects the pain-relieving drugs have on the results or interpretation of the outcomes in research, teaching, or tests.

ITEM 7 - For regulatory testing, provide the requesting Federal Agency and the specific Code of Federal Regulations that requires the test.

ATTACH FORM TO THE ANNUAL REPORT

Privacy Act Notice

Authority: The Animal Welfare Act (AWA), 7 U.S.C. 2131 *et seq*., and the regulations issued thereunder, 9 CFR parts 1 through 4; and the Horse Protection Act (HPA), 15 U.S.C. 1821 *et seq*., and the regulations issued thereunder, 9 CFR parts 11 and 12.

Purpose: This system supports APHIS' administrative activities and enforcement of the AWA and HPA.

Routine Uses:

In addition to those disclosures generally permitted under 5 U.S.C. 552a (b) of the Privacy Act, records maintained in the system may be disclosed outside USDA as follows:

(1) APHIS may disclose the name, city, State, license or registration type and/or status, or change of a license or registrant to any person pursuant to 9 CFR 2.38(c) and 2.127;

(2) APHIS may disclose annual reports submitted to APHIS by licensees and research facilities to any person pursuant to 9 CFR 2.7 and 2.36;

(3) APHIS may disclose inspection reports and other regulatory correspondence issued to licensees and registrants [from the agency] to any attending veterinarian in order to carry out duties under the AWA pursuant to 9 CFR 2.33 and 2.40;

(4) APHIS may disclose the name, telephone number and other contact information, location, inspection reports, and regulatory and other correspondenceof licensees, registrants, permitees, and applicants for the same, to appropriate Federal, foreign, State, local, Tribal, or other public authority agencies or officials, in order to carry out duties under the AWA or State, local, Tribal or other public authority on the same subject pursuant to 7 U.S.C. 2145(b);

(5) APHIS may disclose inspection reports of licensees and registrants, and permit status, to any pet store or other entity that is required under State, local,Tribal, or other public authority to verify a licensee, registrant, or permitee's compliance with the AWA;

(6) APHIS may disclose information to the National Academies of Sciences, Engineering, and Medicine, and any other research institution engaged or approved by the Department, to the extent APHIS deems the disclosure necessary to complete research and/or compile a report in furtherance of the Department's mission;

(7) APHIS may disclose final adjudicatory AWA and HPA decisions or orders by an appropriate authority to any person;

(8) APHIS may disclose to any person the name, city, and State or other information to the extent necessary for proper identification of persons (referred to as "Designated Qualified Persons" or "DQPs") that are or have been qualified to detect and diagnose a horse that is sore or otherwise inspect horses for purposes of enforcing the HPA and of horse industry organizations or associations (referred to as "HIOs") that have currently or have had in the past DQP programs certified by the USDA;

(9) APHIS may disclose to any regulated horse owner, HIO, and other entities responsible for licensure or required to verify compliance with the HPA, HPA inspection findings and regulatory and other correspondence issued to persons or entities regulated under the HPA;

(10) APHIS may disclose to any person the name, city, and State or other information to the extent necessary for proper identification of any person or entity who has been disqualified, suspended, and/or otherwise prohibited from showing or exhibiting any horse, or judging or managing any horse show, horse exhibition, horse sale, or horse auction under the HPA and the terms of such action;

(11) APHIS may disclose to any person the name, city, and State or other information to the extent necessary for proper identification of any regulated individual or entity whose license or permit has been suspended, revoked, expired, terminated, or denied under the AWA and the terms of such action;

(12) APHIS may disclose to appropriate law enforcement agencies, entities, and persons, whether Federal, foreign, State, local, or Tribal, or other public authority responsible for enforcing, investigating, or prosecuting an alleged violation or a violation of law or charged with enforcing, implementing, or complying with a statute, rule, regulation, or order issued pursuant thereto, when a record in this system on its face, or in conjunction with other records, indicates a violation or potential violation of law, whether civil, criminal, or regulatory in nature, and whether arising by general statute or particular program statute, or by regulation, rule, or court order issued pursuant thereto, if the information disclosed is relevant to any enforcement, regulatory, investigative, or prosecutive responsibility of the receiving entity;

(13) APHIS may disclose to the Department of Justice when the agency, or any component thereof, or any employee of the agency in his or her official capacity, or any employee of the agency in his or her individual capacity where the Department of Justice has agreed to represent the employee, or the United States, in litigation, where the agency determines that litigation is likely to affect the agency or any of its components, is a party to litigation or has an interest in such litigation, and the use of such records by the Department of Justice is deemed by the agency to be relevant and necessary to the litigation; provided, however, that in each case, the agency determines that disclosure of the records to the Department of Justice is a use of the information contained in the records that is compatible with the purpose for which the records were collected;

(14) APHIS may disclose information in this system of records to a court or adjudicative body in administrative, civil, or criminal proceedings when: (a) The agency or any component thereof; or (b) any employee of the agency in his or her official capacity; or (c) any employee of the agency in his or her individual capacity where the agency has agreed to represent the employee; or (d) the United States Government, is a party to litigation or has an interest in such litigation, and by careful review, the agency determines that the records are to be for a purpose that is compatible with the purpose for which the agency collected the records;

(15) APHIS may disclose information from this system of records to appropriate agencies, entities, and persons when: (a) USDA suspects or has confirmed that there has been a breach of the system of records; (b) USDA has determined that as a result of the suspected or confirmed breach there is a risk of harm to individuals, USDA (including its information systems, programs, and operations), the Federal Government, or national security; and (c) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with USDA's efforts to respond to the suspected or confirmed compromise and prevent, minimize, or remedy such harm;

(16) APHIS may disclose information from this system of records to another Federal agency or Federal entity, when the USDA determines that information from this system of records is reasonably necessary to assist the recipient agency or entity in (a) responding to a suspected or confirmed breach or (b) preventing, minimizing, or remedying the risk of harm to individuals, the recipient agency or entity (including its information systems, programs, and operations), the Federal Government, or national security, resulting from a suspected or confirmed breach;

(17) APHIS may disclose information in this system of records to USDA contractors and other parties engaged to assist in administering the program, analyzing data, developing information management systems, processing Freedom of Information Act requests, and conducting audits. Such contractors and other parties will be bound by the nondisclosure provisions of the Privacy Act;

(18) APHIS may disclose information in this system of records to USDA contractors, partner agency employees or contractors, or private industry employed to identify patterns, trends, or anomalies indicative of fraud, waste, or abuse;

(19) APHIS may disclose information in this system of records to a Congressional office from the record of an individual in response to any inquiry from that Congressional office made at the written request of the individual to whom the record pertains;

(20) APHIS may disclose information in this system of records to the National Archives and Records Administration or to the General Services Administration for records management activities conducted under 44 U.S.C. 2904 and 2906; and

(21) APHIS may disclose information in this system of records to the Treasury Department as necessary to carry out any and all functions within their jurisdiction, including but not limited to, processing payments, fees, collections, penalties, and offsets.

Disclosure: Furnishing this information is voluntary; however, failure to furnish this information may impede your ability to comply with the requirements of the Animal Welfare Act, regulations, and standards.