



United States Department of Agriculture
Animal and Plant Health Inspection Service

DCARE
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Inspection Report

MEDICAL EDUCATION & RESEARCH INSTITUTE
44 S. CLEVELAND
MEMPHIS, TN 38104

Customer ID: **1009**

Certificate: **63-R-0113**

Site: 001

MEDICAL EDUCATION &
RESEARCH INST.

Type: ROUTINE INSPECTION

Date: 05-AUG-2021

2.31(d)(1)(ii)

Institutional Animal Care and Use Committee (IACUC).

Protocols #208, #209, #202, #210, and #205, involve procedures that cause more than momentary or slight pain or distress to animals (with the provision of anesthesia and/or analgesia), but these protocols do not include a written narrative description of the methods or sources used to determine that alternatives were not available. Facility personnel stated that literature searches for alternatives were no longer required as part of the facility's protocol submission process because in the past literature or database searches had not produced useful results.

Animals who experience more than momentary or slight pain or distress may experience discomfort, stress, pain, or fear. The IACUC must ensure that alternatives are considered for procedures that cause more than momentary or slight pain or distress to animals.

Correct by 09/30/2021 by ensuring that the IACUC requires investigators to document the methods and sources used to determine that alternatives to painful or distressful procedures were not available. Corrections must be made for any currently active protocols as well as for all future proposed activities.

2.31(d)(2)

Critical

Institutional Animal Care and Use Committee (IACUC)

Prepared By: DIANA CARE

USDA, APHIS, Animal Care

Date:

Title: VETERINARY MEDICAL
OFFICER

Received by Title: Facility Representative

Date:



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The IACUC routinely uses a consultant (this individual is not a voting member of the IACUC) to review and approve protocols.

Protocols #208, #209, #191, #210, and #205 involve more than momentary pain or distress with the provision of anesthesia or analgesia. These protocols were approved only by the consultant and were not approved by full IACUC review or by a designated voting member of the IACUC committee.

IACUC oversight of activities using animals is essential for ensuring animal welfare and compliance with the Animal Welfare Act.

Correct by September 30th, 2021 by ensuring that the IACUC approval process is conducted in accordance with the Animal Welfare Act regulations including having a member of the IACUC approve all active protocols.

2.31(d)(4)

Institutional Animal Care and Use Committee (IACUC).

The IACUC failed to notify the principal investigators (PIs) in writing of its decision to approve protocols #208, #209, #210, #205, and #191.

Written notification of IACUC approval for proposed activities involving animals is important to maintain records regarding which protocols and their amendments have been approved. IACUC functions as an oversight committee to help monitor animal welfare in research and written records confirm the IACUC is functioning as required by the Animal Welfare Act.

Correct by 09/30/21 by ensuring all IACUC decisions regarding approval of proposed activities involving animals are provided in writing to the principal investigators and the research facility. This written notification must include the approval, the decision to withhold approval, and/or the decision to require modifications of proposed animal activities.

2.31(e)(1)

Institutional Animal Care and Use Committee (IACUC).

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Protocol #208 does not include a complete description of animal use. The protocol does not include details describing anesthesia, surgery, or wound closure. The procedure states that the surgeon will laparoscopically remove the gall bladder and kidney, and will perform a bowel resection, but does not include any further information about how these procedures are done such as whether the surgery will be performed aseptically or the length of bowel resected. The protocol then states that "the abdomen will then be opened to demonstrate an open laparotomy" but the location and size of the incision is not described, and any tissue handling or manipulations performed during the open laparotomy are not described. The protocol does not state if or how anesthesia will be monitored. An IACUC-approved SOP exists for anesthesia, but is not referenced in protocol #208 and was not included as part of the protocol review process.

Protocol #205 states that paralytics are needed, but does not describe specific drugs or methods used to include paralysis. Surgical prep and anesthesia monitoring are not described.

Protocol #209 does not include a complete description of animal use. The protocol states that "animals will be anesthetized" but does not include information about anesthetic monitoring, intubation, or intra-operative thermal support (all of which the facility does provide for animals on the protocol). Surgical preparation is not described.

Protocol #191 and #210 do not include information about intubation, surgical preparation, surgical technique, or aseptic technique. Facility personnel stated that intubation, surgical preparation, and aseptic technique are used.

The facility's "MERI Veterinary Standard Operating Procedure Manual" (rev 4/9/19) states that Principal Investigator will provide "a detailed step-by-step description of the procedure to be performed".

None of these protocols mention the use of IV catheters or administration of IV fluids, but these procedures are described in the MERI Veterinary Standard Operating Procedure Manual (rev 4/9/19). It is unclear if these procedures are used in any given protocol.

A full description of proposed activities involving animals (and any proposed changes to activities involving animals) is

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required for the IACUC to be able to make an informed determination whether the proposed activities ensure the humane and judicious use of animals in research.

Correct by ensuring proposals to conduct activities involving animals contain a complete description, in lay terms and in detail, of the proposed use of the animals. Additionally, ensure that any of the protocols listed above for which activities are still occurring or may occur in the future are amended to add a complete description of activities and resubmitted to the IACUC for review and approval. Correct by 09/30/2021.

2.32(a)

Personnel qualifications.

The facility does not ensure training of staff, course instructors, or investigators on the topics of humane methods of animal maintenance and experimentation; the concept, availability and use of methods to limit the use of animals or minimize animal distress; proper use of anesthetics, analgesics, and tranquilizers; methods for reporting deficiencies in animal care and treatment; and utilization of services available to provide information on alternatives to the use of live animals in research and the intent and requirements of Animal Welfare Act.

Training personnel in the use of animals in research, ways to minimize pain and distress for animals, and the intent and requirements of the Animal Welfare Act, is essential for ensuring animal welfare and compliance with the Animal Welfare Act regulations. Personnel who do not have adequate training may fail to care for animals properly, may fail to consider alternatives to painful or distressful procedures, and may fail to recognize or understand programmatic shortcomings related to compliance with the Animal Welfare act.

Correct by 09/30/2021 by ensuring all people involved in animal care or research are trained in accordance with The Animal Welfare Act, as described in 2.32(a).

This inspection and exit interview were conducted with facility representatives.

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Species Inspected

Cust No	Cert No	Site	Site Name	Inspection
1009	63-R-0113	001	MEDICAL EDUCATION & RESEARCH INST.	05-AUG-2021

Count	Scientific Name	Common Name
000000	NONE	NONE
000000	Total	