



Inspection Report

East Tennessee Clinical Research Inc
80 COPPER RIDGE FARM RD
ROCKWOOD, TN 37854

Customer ID: **39091**
Certificate: **63-R-0120**
Site: 001

EAST TENNESSEE CLINICAL
RESEARCH INC

Type: ROUTINE INSPECTION
Date: 18-SEP-2025

2.31(e) Repeat

Institutional Animal Care and Use Committee (IACUC).

One of the registrant's study protocols is missing required components. Protocol 24-1212 does not state the total approximate number of animals to be used in the study and rationale for that number, a complete description of the procedures of the proposed use of the animals, and the point at which animals that are experiencing problems would be removed from study to prevent animals being subjected to procedures and unnecessary pain or distress beyond that which is necessary for scientifically valuable research.

Incomplete protocols do not allow the IACUC to fully understand and review the proposed activities involving animal use. This oversight is crucial to monitoring and enforcing animal welfare standards in research.

All protocols submitted to the IACUC for review must contain all five components listed in this subsection, including the species and the approximate number of animals to be used, a rationale for the species and number of animals, a complete description of the proposed use of the animals, a description of procedures designed to assure that discomfort and pain to the animals will be limited to that which is unavoidable for the conduct of scientifically valuable research, and a description of any euthanasia method to be used.

2.33(a)(1)

Attending veterinarian and adequate veterinary care.

The current written Program of Veterinary Care (PVC) does not include veterinary care for swine, which is occasionally a regulated species at the facility. The Attending Veterinarian evaluates the swine at this facility, but the guidance provided to the licensee is not documented in the PVC.

Not having all covered animals at a facility included in the PVC can result in potential suboptimal veterinary care and daily observations. Each research facility shall employ an attending veterinarian under formal arrangements. In the case of a part-time attending veterinarian or consultant arrangements, the formal arrangements shall include a written program of veterinary care and regularly scheduled visits to the research facility.

Correct by October 23, 2025

Prepared By: SHOSHANA TANENBAUM

USDA, APHIS, Animal Care

Date:

25-SEP-2025

Title: VETERINARY MEDICAL
OFFICER

Received by Title: Facility Representative

Date:

25-SEP-2025



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2.33(b)(3) Critical

Attending veterinarian and adequate veterinary care.

The facility did not communicate information on an animal health problem to the attending veterinarian in a timely manner. Dog XGU-4 developed blood in her feces and staff understood this to be a possible result of the experimental procedure. Daily observations document 11 instances of blood in XGU-4's feces between June 6 and June 25, 2025. On June 25, 2025, the 11th instance, facility records document that the dog had not eaten in 24 hours. A licensed veterinary technician examined XGU-4, observed pale gums and slight lethargy, and determined that a veterinarian needed to examine the animal. A veterinarian examined XGU-4 and determined the dog needed to be treated immediately for her well-being. XGU-4 lost 0.45 kg (approximately 1 lb.) between May 21, 2025 where she weighed 9.50 kg and July 1, 2025 where she weighed 9.05 kg. The attending veterinarian told USDA inspectors that she had not received communication regarding this dog. There are no parameters for when to address bloody feces in the experimental protocol nor in the Program of Veterinary Care.

While staff conducted daily observations of all animals to assess their health and well-being, there was a failure of the required direct and frequent communication from the staff to the attending veterinarian to ensure that timely and accurate information on problems of animal health, behavior and well-being are conveyed to the attending veterinarian. Failure to communicate those problems to a veterinarian can result in prolonged medical conditions and ongoing pain/distress.

The registrant must ensure that daily observation of all animals is conducted to assess their health and well-being. They must also ensure that a mechanism of direct and frequent communication is in place so that timely and accurate information on problems of animal health, behavior, and well-being is conveyed to the attending veterinarian.

To be corrected from this date forward: September 25, 2025

This inspection and exit interview were conducted with facility representatives.

Prepared By: SHOSHANA TANENBAUM

USDA, APHIS, Animal Care

Date:

25-SEP-2025

Title: VETERINARY MEDICAL
OFFICER

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Species Inspected

Cust No	Cert No	Site	Site Name	Inspection
39091	63-R-0120	001	EAST TENNESSEE CLINICAL RESEARCH INC	18-SEP-2025

Count	Scientific Name	Common Name
000006	<i>Canis familiaris</i>	DOG ADULT
000007	<i>Felis catus</i>	CAT ADULT
000002	<i>Felis catus</i>	CAT KITTEN
000000	<i>Sus scrofa domestica</i>	DOMESTIC PIG / POTBELLY PIG / MICRO PIG
000015	Total	