



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: 05-AUG-2024

2.31(c)(3)

Repeat

Institutional Animal Care and Use Committee (IACUC).

The written report to the Institutional Official dated June 11, 2024 of the IACUC's semi-annual inspections conducted late May/early June 2024 do not include all the required information. The report does not include a description of the nature and extent of the research facility's adherence to the regulations regarding the review of the program of humane care and use of animals. The report includes multiple deficiencies identified during the facility inspection but does not identify whether the deficiencies are minor or significant. In addition, there is no specific plan and schedule with dates for correcting the deficiencies. For example one identified deficiency stated only 'several paint chips were noticed on the floor of C1, C2 and the treatment room'. No correction plan or date for correction were identified nor was there a designation of minor or significant. Another example is that 'resting platforms that are starting to warp should be considered to be replaced as soon as possible'. No correction date was given and no designation of minor or significant was made. The semi-annual evaluation report is required to notify the Institutional Official of the status of the facility's adherence to the AWA regulations and standards. The IACUC and IO need this information to be able to address correction of all deficiencies and to notify USDA of any significant deficiency that remains uncorrected.

The facility shall prepare reports of its semi-annual program review and facility inspection and submit the reports to the IO. The reports shall contain a description of the nature and extent of the facility's adherence to the Animal Welfare Act, specify each departure and identify it as minor or significant, and contain a reasonable and specific plan and schedule with dates for correcting each deficiency.

2.31(e)(4)

Institutional Animal Care and Use Committee (IACUC).

Protocol 24-313 does not include a complete description of the sedation to be used. The protocol states that 'ear duct flushing will be performed under sedation' and then describes how the procedure will be performed. However, there was no description of the drug to be used for the sedation including such details as the name of the drug, route of administration, dosage or recovery monitoring. A description of procedures regarding sedation are necessary in a proposal to conduct animal activities in order to ensure that the IACUC has all information needed to approve animal activities, that all staff understand what the approved procedures are, and that discomfort and pain will be appropriately limited for the animals.

Proposal 24-313 must contain a description of procedures designed to assure that discomfort and pain to animals will be limited including the provision for the use of analgesic, anesthetic and tranquilizing drugs where indicated and

Prepared By: SUSANNE BRUNKHORST

USDA, APHIS, Animal Care

Date:

07-AUG-2024

Title: VETERINARY MEDICAL
OFFICER

Received by Title: Registrant

Date:

07-AUG-2024



Inspection Report

appropriate.
Correct by 9/7/24.

This inspection and exit interview were conducted with the registrant and multiple facility representatives.

Prepared By: SUSANNE BRUNKHORST
USDA, APHIS, Animal Care

Title: VETERINARY MEDICAL
OFFICER

Date:
07-AUG-2024

Received by Title: Registrant

Date:
07-AUG-2024



Species Inspected

Cust No	Cert No	Site	Site Name	Inspection
39091	63-R-0120	001	EAST TENNESSEE CLINICAL RESEARCH INC	05-AUG-2024

Count	Scientific Name	Common Name
000058	<i>Canis familiaris</i>	DOG ADULT
000060	<i>Felis catus</i>	CAT ADULT
000118	Total	