

United States Department of Agriculture Animal and Plant Health Inspection Service

SBRUNKHORST INS-0000874559

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: 20-JUN-2023

2.31(c)(3)

Institutional Animal Care and Use Committee (IACUC).

The written reports of the IACUC's semi-annual evaluations of the program of humane care and use review and facility inspection do not include all the required information.

*The Nov 8, 2022 and May 10, 2023 evaluation reports both state the basis used for the semiannual program of humane care and use review but do not include a description of the nature and extent of the research facility's adherence to the regulations.

*The Nov 8, 2022 and May 10, 2023 evaluation reports both state that one deficiency related to flooring paint was found during the facility inspection. The departure was identified but was not distinguished as minor or significant and there was no specific plan and schedule with dates for correcting the deficiency. It could not be ascertained from the reports whether the deficiency had not been corrected or had reoccurred between the two semi-annual evaluations.

*Checklists used to conduct the semi-annual facility inspection showed that the new animal housing location was inspected by a sub-committee of the IACUC on June 9, 2023 but the evaluation report to the Institutional Official was dated and sent to the IO on May 10, 2023. Three facility related issues were noted on the June 9, 2023 checklist. These issues would not have been discussed at the May 10, 2023 IACUC meeting and thus were not addressed by the IACUC at that meeting or in the semi-annual evaluation report.

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 Institutional Official need this information to be able to address correction of all deficiencies and notify USDA APHIS 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 Institutional Official. The reports shall be signed by a majority of the IACUC members, 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. Correct by Dec. 1, 2023.

2.31(d)(1)(ii)

Institutional Animal Care and Use Committee (IACUC).

Protocol 22-0285 contains a description of a surgical skin biopsy procedure. The description of the procedure included the use of anesthetics and analgesics. No alternative search narrative was included in this IACUC approved protocol. An alternative search for potentially painful and/or distressful procedures should be done to help avoid or minimize

	SUSANNE BRUNKHORST VETERINARY MEDICAL OFFICER	Date: 21-JUN-2023	
Received by Title:	Registrant		Date: 21-JUN-2023



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discomfort,	distress	and	pain	to	the	animals.

In order to approve proposed activities the IACUC shall determine that the principal investigator has considered alternatives to procedures that may cause more than momentary or slight pain or distress to the animals and has provided a written narrative description of the methods and sources used to determine that alternatives were not available. Correct by 6/30/23.

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

Prepared By: SUSANNE BRUNKHORST Date:

USDA, APHIS, Animal Care
Title: VETERINARY MEDICAL

OFFICER

Received by Title: Registrant Date:

21-JUN-2023

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Species Inspected

Cust No	Cert No	Site	Site Name	Inspection
39091	63-R-0120	001	EAST TENNESSEE CLINICAL RESEARCH INC	20-JUN-2023

CountScientific NameCommon Name000069Canis familiarisDOG ADULT000008Sus scrofa domesticaDOMESTIC PIG / POTBELLY PIG / MICRO PIG

000077 **Total**