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: 02-JUN-2021

2.31(e)(3)

Institutional Animal Care and Use Committee (IACUC).

Several protocols reviewed did not contain a complete description of the proposed use of the animals.

*Protocol 20-0256 stated that in addition to daily general health observations 'clinical health observations' would be made on specific days throughout the study. There was no description in the protocol of what these clinical health observations included, who was to perform them or what should be done if abnormalities were observed.

*Protocol 20-0254 stated that in addition to daily general health observation 'targeted safety observations' would be made on specific days throughout the study. There was no description of what these observations included, who was to perform them or what should be done if abnormalities were observed.

*Protocols 21-0261 and 21-0265 both referenced the use of one or two scoring systems (for pyoderma and for erythema) but did not include descriptions of the systems or how they were to be used to ensure the health and welfare of the animals.

*Protocols 21-0261 and 21-0265 both included minor surgical procedures that cause more than momentary pain or distress (multiple punch biopsies closed with sutures). The protocols did not include a description of these procedures to include such details as use of aseptic techniques, type of suture material to be used, and post-operative monitoring/care.

*Protocol 21-0265 includes the use of a compound known to cause erythema in people. The protocol did not address the

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potential issues with erythema in the animals. No monitoring system or plan for alleviation of any erythema effects if noted was included in the protocol.

A complete description of the use of the animals is necessary in a protocol to ensure that all research staff and IACUC members are aware of the details regarding the study activities being conducted on the animals and the parameters in place to assure the health and comfort of the animals. In addition, the IACUC members need a complete description to understand the proposed use of the animals in order to approve the protocol and to assure compliance with regulatory requirements.

The studies referenced in the above protocols have all been completed. All future proposals to conduct an activity involving animals or to make a significant change to an ongoing activity involving animals, must contain a complete description of the proposed use of the animals. Correct by June 7, 2021.

This inspection was conducted with an animal caretaker and the IACUC chair. The exit interview was conducted with the IACUC chair.

United States Department of Agriculture
Animal and Plant Health Inspection Service

Customer: 39091
Inspection Date: 02-Jun-2021

Species Inspected

Cust No	Cert No	Site	Site Name	Inspection
39091	63-R-0120	001	EAST TENNESSEE CLINICAL RESEARCH INC	02-JUN-2021

Count	Scientific Name	Common Name
000018	*Canis lupus familiaris*	DOG ADULT
000018	**Total**	