

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER

250 Marquette Ave, Ste. 600
Minneapolis, MN 55401
(612) 334-4100 Fax: (612) 334-4134

DATE(S) OF INSPECTION

7/7/2025-7/11/2025

FEI NUMBER

3029067611

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Robert J. Schumacher, PhD, Scientific Director

FIRM NAME

Center for Translational Medicine

STREET ADDRESS

516 Delaware St SE, Room 7-227,
University of Minnesota

CITY, STATE, ZIP CODE, COUNTRY

Minneapolis, MN 55455-6301

TYPE ESTABLISHMENT INSPECTED

Nonclinical Laboratory

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

The final study report did not include a description of all circumstances that may have affected the quality or integrity of the data.

Specifically, (b) (4) as well as any instruments used to monitor temperature during (b) (4) and (b) (4) were not identified in the source records for any of the subjects for the (b) (4) study.

OBSERVATION 2

The study director failed to assure that the protocol, including any change, was approved and was followed.

Specifically, (b) (4) clinical observations related to alopecia were documented in the source records for (b) (4) of (b) (4) subjects but were not included in the (b) (4) Report of the (b) (4) Final Report as required by the protocol. For example,

Subject ID	Abnormal Finding	Recorded Dates
(b) (4)	(b) (4)	(b) (4)
(b) (4)	(b) (4)	(b) (4)
(b) (4)	(b) (4)	(b) (4)
(b) (4)	(b) (4)	(b) (4)
(b) (4)	(b) (4)	(b) (4)
(b) (4)	(b) (4)	(b) (4)

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OF THIS PAGE**

EMPLOYEE(S) SIGNATURE

Chelsea W Lamm, Investigator

Chelsea W Lamm
Investigator
Signed By: CHELSEA W. LAMM -
S
Date Signed: 07-11-2025
15:00:41

X

DATE ISSUED

7/11/2025

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<small>NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED</small> Robert J. Schumacher, PhD, Scientific Director			
<small>FIRM NAME</small> Center for Translational Medicine		<small>STREET ADDRESS</small> 516 Delaware St SE, Room 7-227, University of Minnesota	
<small>CITY, STATE, ZIP CODE, COUNTRY</small> Minneapolis, MN 55455-6301		<small>TYPE ESTABLISHMENT INSPECTED</small> Nonclinical Laboratory	
<div style="display: flex; justify-content: space-between; align-items: center;"> (b) (4) (b) (4) (b) (4) </div>			
OBSERVATION 3 Standard operating procedures have not been established for test system observations and handling of (b) (4) (b) (4) or (b) (4) during study. Specifically, for the (b) (4), (b) (4), and (b) (4) studies, the firm completed test system observations and took actions for (b) (4) or (b) (4). However, no standard operating procedures were established that describe these processes.			
OBSERVATION 4 The quality assurance unit failed to maintain a copy of a master schedule sheet that contained all required elements for all nonclinical laboratory studies conducted by the testing facility. Specifically, (b) (4) procedures including (b) (4) preparation, (b) (4), test system observations, (b) (4) (b) (4) data collection, and sample collection were performed by the firm for the (b) (4) (b) (4) and (b) (4) studies. However, no master schedule was maintained listing these (b) (4) studies.			
OBSERVATION 5 The study director failed to assure that all raw data, documentation, protocols, specimens, and final reports were transferred to the archives during or at the close of the study. Specifically, (b) (4) and the (b) (4) signed Amendment (b) (4) of the protocol for the (b) (4) study were not transferred to the archives after the study was completed on (b) (4). A copy of (b) (4) (b) (4) was not (b) (4) as reported in the Compliance section of the (b) (4) Final Report, until (b) (4).			
SEE REVERSE OF THIS PAGE	<small>EMPLOYEE(S) SIGNATURE</small> Chelsea W Lamm, Investigator		<small>DATE ISSUED</small> 7/11/2025 <div style="font-size: small; text-align: center;"> Chelsea W Lamm Investigator Signed By: CHELSEA W. LAMM - S Date Signed: 07-11-2025 15:00:41 X </div>

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Investigator
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The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."