DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
US Customhouse Rm900 200 Chestnut St Philadelphia, PA 19106 (215)597-4390 Ext:4200 Fax:(215)597-0875	2/10/2026-3/3/2026* FEI NUMBER 3042047166

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Dennis J. Hsu, M.D, Clinical Investigator	
FIRM NAME Dennis J. Hsu, M.D	STREET ADDRESS UPMC Hillman Cancer Center, 5115 Centre Ave
CITY, STATE, ZIP CODE, COUNTRY Pittsburgh, PA 15232-1301	TYPE ESTABLISHMENT INSPECTED Clinical Investigator

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

An investigation was not conducted in accordance with the signed statement of investigator.

Specifically, Protocol version dated 8/25/22, section 9.3.1 Expedited Reporting Requirements for Adverse Events, requires grade 3 serious adverse events (SAE) not resulting in hospitalization greater than or equal to 24 hours, be reported to the National Cancer Institute (NCI) via CTEP-AERS no greater than 10 calendar days from awareness of the event.

☐ Subject (b) (6), (b) (7)(C) experienced an SAE on 8/27/22 to 9/7/22. The site became aware of the SAE on 9/13/22. The SAE was not reported via CTEP-AERS until 11/30/22.

*DATES OF INSPECTION

2/10/2026(Tue), 2/11/2026(Wed), 2/12/2026(Thu), 2/17/2026(Tue), 2/18/2026(Wed), 2/23/2026(Mon), 2/26/2026(Thu), 2/27/2026(Fri), 3/02/2026(Mon), 3/03/2026(Tue)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Brittany M Kershaw, Investigator	X Brittany M Kershaw Investigator Signed By: Brittany M. Kershaw - S Date Signed: 03-03-2026 12:44 54	3/3/2026

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."