DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
555 Winderley Place, Suite 200 Maitland, FL 32751 (407)475-4700 Fax:(407)475-4768	6/2/2025-6/13/2025* FEI NUMBER 3014441387

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Stephen J. Fallon, Clinical Investigator

FIRM NAME	STREET ADDRESS
Stephen J. Fallon PhD	1401 NE 26th Street
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Wilton Manors, FL 33305	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 WE OBSERVED:
The following observations were noted regarding the conduct of Protocol (b)(4).

OBSERVATION 1
Informed consent was not properly documented in that the written informed consent used in the study was not signed by the subject or the subject's legally authorized representative at the time of consent and was not dated by the subject or the subject's legally authorized representative at the time of consent.

Specifically,

1. Informed consent was not obtained for subject (b) (6), (b) (7)(C) prior to screening activities.

2. For 35 of 42 subjects reviewed, the informed consent form was not dated by the subject. Study coordinators dated the consent form on behalf of those 35 subjects.

3. Subject (b) (6), (b) (7)(C) did not date the consent form at the time of consent.

***DATES OF INSPECTION**
6/02/2025(Mon), 6/03/2025(Tue), 6/04/2025(Wed), 6/05/2025(Thu), 6/06/2025(Fri), 6/12/2025(Thu), 6/13/2025(Fri)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Emily C Caldwell, Investigator Ricardo Vela, Investigator X Emily C Caldwell Investigator Signed By: Emily C. Caldwell -S Date Signed: 06-13-2025 09:18:33	6/13/2025

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."