DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10 Waterview Blvd., 3rd Floor Parsippany, NJ 07054 (973)331-4900	3/5/2026-3/11/2026* FEI NUMBER 3012733828

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
John L. Bucek, IRB Chairman

FIRM NAME	STREET ADDRESS
Somerset Medical Center IRB	110 Rehill Ave
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Somerville, NJ 08876-2519	Institutional Review Board

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

For other than expedited reviews, research approved by the IRB does not always receive the approval of a majority of those IRB members present.

Specifically, the review of IRB meeting minutes from 2018 to 2025 revealed that quorum was not met during convened meetings held on the following dates:

- March 17, 2020
- July 20, 2021
- November 16, 2021
- July 16, 2024
- January 21, 2025

The March 17, 2020 meeting minutes indicate that the IRB achieved quorum of seven members entirely through e-mail voting to grant initial approval of a humanitarian use device study, and to approve the previous meeting's minutes.

The July 20, 2021 meeting minutes indicate that only five voting members were present, rendering the quorum deficient of the required six members. However, the IRB proceeded to approve the previous meeting's minutes by incorporating an e-mail vote from a member who was not present at the meeting.

The November 16, 2021 meeting minutes indicate that only five voting members were present, rendering the quorum deficient of the required six members. The IRB proceeded to approve the previous

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Jay B Shah, Investigator X Jay B Shah Investigator Signed By: 2003178113 Date Signed: 03-11-2026 14:56:04	3/11/2026

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meeting's minutes and two research proposals by incorporating e-mail votes from two members who were not in attendance.

The July 16, 2024 meeting minutes indicate that only four members were present, although a quorum of six members was required. The IRB proceeded to approve the previous meeting's minutes by incorporating e-mail votes from two members who were not in attendance.

The January 21, 2025 meeting minutes indicate that this meeting was canceled. However, the IRB approved the previous meeting's minutes entirely through e-mail voting, outside of a convened session.

***DATES OF INSPECTION**
3/05/2026(Thu), 3/06/2026(Fri), 3/10/2026(Tue), 3/11/2026(Wed)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Jay B Shah, Investigator	X Jay B Shah Investigator Signed By: 2003178113 Date Signed: 03-11-2026 14:56:04	DATE ISSUED 3/11/2026

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."