DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
109 Holton Street Winchester, MA 01890 (781)587-7500 Fax:(781)587-7556	1/28/2026-2/2/2026* FEI NUMBER 1283379

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Jennifer L. Pacheco, MPH, CHRC, CIM, CIP Director of Healthcare Research Compliance

FIRM NAME	STREET ADDRESS
Baystate Medical Center IRB	3601 Main St
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Springfield, MA 01107-1116	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 WE OBSERVED:

OBSERVATION 1

Minutes of IRB meetings have not been prepared in sufficient detail to show actions taken by the IRB and the vote on actions, including the number of members voting for, against and abstaining.

Specifically,

A) For study (b) (4) ID (b) (4)/(b) (4) number (b) (4) , the IRB meeting minutes from Jan 10, 2024, and Dec 11, 2024, contain identical verbatim descriptions of a discussion regarding a noted error. The identical wording in minutes from two separate meetings does not accurately reflect the actions taken by the IRB at each meeting or the status of the issue at the time of the Dec 11, 2024, meeting.

B) The IRB meeting minutes from the convened meeting held on Apr 28, 2025, did not document the number of members voting for, against, or abstaining for actions taken on the studies reviewed.

*DATES OF INSPECTION

1/28/2026(Wed), 1/29/2026(Thu), 1/30/2026(Fri), 2/02/2026(Mon)

X Agata E Libera
Investigator
Signed By: AGATA E. LIBERA -S
Date Signed: 02-02-2026 13:57:05

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Jose A Torres, Investigator Agata E Libera, Investigator X Jose A Torres Investigator Signed By: 2003135324 Date Signed: 02-02-2026 13:56:23	2/2/2026

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."