

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION					
<small>DISTRICT ADDRESS AND PHONE NUMBER</small> 10 Waterview Blvd., 3rd Floor Parsippany, NJ 07054 (973) 331-4900		<small>DATE(S) OF INSPECTION</small> 12/1/2025-12/4/2025 <small>FEI NUMBER</small> 2243630			
<small>NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED</small> Amanda A O'Hara, Director, Research Integrity					
<small>FIRM NAME</small> Cooper Health System IRB		<small>STREET ADDRESS</small> 401 Haddon Ave			
<small>CITY, STATE, ZIP CODE, COUNTRY</small> Camden, NJ 08103-1505		<small>TYPE ESTABLISHMENT INSPECTED</small> Institutional Review Board			
<p>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.</p>					
<p>DURING AN INSPECTION OF YOUR FIRM I OBSERVED:</p> <p>OBSERVATION 1</p> <p>The IRB has no written procedure for determining which projects require review more often than annually and need verification from sources other than the investigator that no material changes have occurred since previous IRB review.</p> <p>Specifically, the written procedures don't describe what factors are used by the IRB to determine protocols requiring review more often than annually. There are no written procedures which address verification from other sources.</p>					
<p>OBSERVATION 2</p> <p>The IRB has no written procedure for reporting its findings and actions to the investigator and institution.</p> <p>Specifically, the written procedures do not address, at a minimum, how and when the findings and actions are reported.</p>					
<p>OBSERVATION 3</p> <p>The IRB has no written procedure for conducting its initial review of research.</p> <p>Specifically, the IRB made six (6) non-significant risk determinations since the last inspection without a medical device study written procedure.</p>					
<p>OBSERVATION 4</p> <p>The IRB has no written procedures for ensuring prompt reporting to appropriate institutional officials and the FDA of any instance of serious or continuing noncompliance with these regulations or the requirements or determinations of the IRB.</p> <p>Specifically, the IRB reported one (1) serious noncompliance event without adequate written procedures to, at minimum, address how and when the noncompliance is to be reported to the FDA and appropriate institutional officials.</p>					
SEE REVERSE OF THIS PAGE		<table border="0" style="width: 100%;"> <tr> <td style="width: 60%; vertical-align: top;"> <small>EMPLOYEE(S) SIGNATURE</small> Gabrielle J Swain, Investigator </td> <td style="width: 40%; vertical-align: top; text-align: center;"> <small>DATE ISSUED</small> 12/4/2025 <div style="font-size: 0.8em;"> Gabrielle J Swain Investigator Signed By: GABRIELLE J. SWAIN Date Signed: 12-04-2025 16:10:29 </div> </td> </tr> </table>		<small>EMPLOYEE(S) SIGNATURE</small> Gabrielle J Swain, Investigator	<small>DATE ISSUED</small> 12/4/2025 <div style="font-size: 0.8em;"> Gabrielle J Swain Investigator Signed By: GABRIELLE J. SWAIN Date Signed: 12-04-2025 16:10:29 </div>
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NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Amanda A O'Hara, Director, Research Integrity

FIRM NAME

Cooper Health System IRB

STREET ADDRESS

401 Haddon Ave

CITY, STATE, ZIP CODE, COUNTRY

Camden, NJ 08103-1505

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OF THIS PAGE**

EMPLOYEE(S) SIGNATURE

Gabrielle J Swain, Investigator

Gabrielle J Swain
Investigator
Signed By: GABRIELLE J. SWAIN
Date Signed: 12-04-2025
16:10:29

X

DATE ISSUED

12/4/2025

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."