

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION					
DISTRICT ADDRESS AND PHONE NUMBER 6th & Kipling St. (P.O. Box 25087) Denver, CO 80225-0087 (303) 236-3000 Fax: (303) 236-3100		DATE(S) OF INSPECTION 2/23/2026-3/3/2026* FEI NUMBER 3013827563			
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Russell U Stolp, System Manager					
FIRM NAME Catholic Health Initiatives Institute for Research and Innovation IRB		STREET ADDRESS 198 Inverness Dr W			
CITY, STATE, ZIP CODE, COUNTRY Englewood, CO 80112-5202		TYPE ESTABLISHMENT INSPECTED Insitutional 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 The IRB approved the conduct of research, but did not determine that informed consent would be appropriately documented. Specifically, CommonSpirit Health Research Institute IRB did not require an IRB approved inform consent form be used for study protocol (b) (4) titled (b) (4) (b) (4)					
*DATES OF INSPECTION 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		<table border="0" style="width: 100%;"> <tr> <td style="width: 60%; vertical-align: top;"> EMPLOYEE(S) SIGNATURE Courtney R Bratina, Investigator </td> <td style="width: 40%; vertical-align: top; text-align: center;"> Courtney R Bratina Investigator Signed By: COURTNEY BRATINA-6 Date signed: 03-03-2026 13:22:38 X </td> </tr> </table>		EMPLOYEE(S) SIGNATURE Courtney R Bratina, Investigator	Courtney R Bratina Investigator Signed By: COURTNEY BRATINA-6 Date signed: 03-03-2026 13:22:38 X
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DATE ISSUED 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."