DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
22215 26th Ave SE Suite 210 Bothell, WA 98021 (425)302-0340 Fax:(425)302-0404	2/23/2026-3/3/2026* FEI NUMBER 3019535

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Laurie J. Price, Senior Director, Office of Institutional Assurances

FIRM NAME	STREET ADDRESS
Seattle Children's Hospital IRB	1900 9th Ave.
CITY, STATE, ZIP CODE, COUNTRY Seattle	TYPE ESTABLISHMENT INSPECTED 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

The IRB does not include at least one member whose primary concerns are in nonscientific areas.

Specifically, there were several primary and alternate IRB members that were identified by the IRB as non-scientists, but who have significant scientific experience, as found in the following table:

Member Initials	Scientific Education	Scientific Work Experience	Other Scientific Experience
(b) (6), (b) (7)	• BA, Biological Sciences and Anthropology • MA, Anthropology • PhD, Biological Anthropology	• Graduate Research Assistant, Molecular Anthropology	• 3+ Scientific publications
(b) (6), (b) (7)	• BA, Medical Anthropology and Global Health		
(b) (6), (b) (7)	• BS, Psychology	• Research	

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
Gavin W Pierce, Investigator

X Gavin W Pierce
Investigator
Signed By: Gavin W. Pierce -S
Date Signed: 03-03-2026
16:03:50

DATE ISSUED
3/3/2026

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
22215 26th Ave SE Suite 210 Bothell, WA 98021 (425)302-0340 Fax:(425)302-0404	2/23/2026-3/3/2026* FEI NUMBER 3019535

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Laurie J. Price, Senior Director, Office of Institutional Assurances

FIRM NAME	STREET ADDRESS
Seattle Children's Hospital IRB	1900 9th Ave.
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Seattle	Institutional Review Board

		• Assistant • Clinical Research Assistant • Clinical Research Coordinator	
(b) (6), (b) (7	• BS, Biochemistry • MS, Biomedical Regulatory Affairs	• Clinical Toxicology Laboratory Technician • Clinical Toxicology Laboratory Lead • Clinical Toxicology Laboratory Supervisor • Regulatory Coordinator Intern – Clinical Trials Unit • Specimen Processing Services Supervisor – Department of Lab Medicine	

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE

Gavin W Pierce, Investigator

X Gavin W Pierce
Investigator
Signed By: Gavin W. Pierce -S
Date Signed: 03-03-2026
16:03:50

DATE ISSUED
3/3/2026

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
22215 26th Ave SE Suite 210 Bothell, WA 98021 (425)302-0340 Fax:(425)302-0404	2/23/2026-3/3/2026* FEI NUMBER 3019535

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Laurie J. Price, Senior Director, Office of Institutional Assurances

FIRM NAME	STREET ADDRESS
Seattle Children's Hospital IRB	1900 9th Ave.
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Seattle	Institutional Review Board

		• Clinical Research Coordinator	
(b) (6), (b) (7)	• BS, Microbiology • Medical Laboratory Science Program Certification	• Medical Laboratory Scientist, Microbiology	
(b) (6), (b) (7)	• BS, Psychology	• Clinical Research Associate • Clinical Research Coordinator • Clinical Research Supervisor • Clinical Research Manager	• 3+ Scientific publications
(b) (6), (b)	• BA, Psychology	• Research Assistant • Research Coordinator • Clinical Research Associate	• 2+ Scientific publications

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE

Gavin W Pierce, Investigator

X Gavin W Pierce
Investigator
Signed By: Gavin W. Pierce -S
Date Signed: 03-03-2026
16:03:50

DATE ISSUED
3/3/2026

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
22215 26th Ave SE Suite 210 Bothell, WA 98021 (425)302-0340 Fax:(425)302-0404	2/23/2026-3/3/2026* FEI NUMBER 3019535

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Laurie J. Price, Senior Director, Office of Institutional Assurances

FIRM NAME	STREET ADDRESS
Seattle Children's Hospital IRB	1900 9th Ave.
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Seattle	Institutional Review Board

		• Clinical Research Coordinator • Clinical Research Supervisor	
(b) (6), (b) (	• BS, Neuroscience	• Laboratory Research Assistant • Clinical Research Assistant • Clinical Research Study Coordinator • Research Coordinator	
(b) (6), (b) (7	• BA, Psychology • MA, Psychology	• Research Assistant • Adjunct Faculty – Statistics for Behavioral Science Labs	

The IRB members listed above were relied upon, either solely or in addition to another IRB member listed above, as fulfilling meeting attendance by a non-scientific member at 32% of meeting minutes reviewed, including the following:

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
22215 26th Ave SE Suite 210 Bothell, WA 98021 (425)302-0340 Fax:(425)302-0404	2/23/2026-3/3/2026* FEI NUMBER 3019535

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Laurie J. Price, Senior Director, Office of Institutional Assurances

FIRM NAME	STREET ADDRESS
Seattle Children's Hospital IRB	1900 9th Ave.
CITY, STATE, ZIP CODE, COUNTRY Seattle	TYPE ESTABLISHMENT INSPECTED Institutional Review Board

Meeting Date	Study	Review	Non-Scientific Member(s)
10/05/2023	(b) (4)	Initial	(b) (6), (b) (7)(C)
05/22/2024		Initial	
06/05/2024		Initial	
06/27/2024		Modification	
03/12/2025		Continuing	
07/30/2025		Continuing	
09/10/2025		Modification	
10/09/2025		Modification	
01/28/2026		Initial Modification	

OBSERVATION 2

The IRB does not include at least one member who is not otherwise affiliated with the institution, and who is not part of the immediate family of a person who is affiliated with the institution.

Specifically, there were not IRB members who were identified as unaffiliated with the institution in 46% of the IRB meeting minutes I reviewed. The following meetings did not have an identified unaffiliated IRB member present:

Meeting Date	Study	Review

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
22215 26th Ave SE Suite 210 Bothell, WA 98021 (425)302-0340 Fax:(425)302-0404	2/23/2026-3/3/2026*
	FEI NUMBER 3019535

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Laurie J. Price, Senior Director, Office of Institutional Assurances

FIRM NAME	STREET ADDRESS
Seattle Children's Hospital IRB	1900 9th Ave.
CITY, STATE, ZIP CODE, COUNTRY Seattle	TYPE ESTABLISHMENT INSPECTED Institutional Review Board

08/04/2021	(b) (4)	Modification & Continuing
07/20/2022		Modification & Continuing
03/29/2023		Initial
05/10/2023		Follow-Up Report
06/29/2023		Modification & Continuing
09/13/2023		Initial
10/05/2023		Initial
12/14/2023		Initial
01/31/2024		Modification
02/14/2024		Initial
10/09/2024		Modification
03/06/2025		Continuing
04/03/2025		Modification Modification & Continuing

***DATES OF INSPECTION**
2/23/2026(Mon), 2/24/2026(Tue), 2/25/2026(Wed), 2/26/2026(Thu), 2/27/2026(Fri), 3/03/2026(Tue)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Gavin W Pierce, Investigator X Gavin W Pierce Investigator Signed By: Gavin W. Pierce -S Date Signed: 03-03-2026 16:03:50	3/3/2026

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
22215 26th Ave SE Suite 210 Bothell, WA 98021 (425)302-0340 Fax:(425)302-0404	2/23/2026-3/3/2026*
	FEI NUMBER 3019535

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Laurie J. Price, Senior Director, Office of Institutional Assurances

FIRM NAME	STREET ADDRESS
Seattle Children's Hospital IRB	1900 9th Ave.
CITY, STATE, ZIP CODE, COUNTRY Seattle	TYPE ESTABLISHMENT INSPECTED Institutional Review Board

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
Gavin W Pierce, Investigator

X Gavin W Pierce
Investigator
Signed By: Gavin W. Pierce -S
Date Signed: 03-03-2026
16:03:50

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."