



Institutional Biosafety Committee
Meeting Minutes

Date: 01/07/2026 Start time: 9:00am (ET) End time: 11:00am (ET)

Advarra IBC meetings are closed to the public to protect confidential and proprietary information as outlined in the Advarra IBC standard operating procedures.

Chair: Darlene Ward

Voting Members Present: Dan Eisenman (Committee Member), Scott Swindle (Committee Member), Nichole Tower (Committee Member), Warren Rummage (Committee Member), Jackie Lomeli (Committee Member), Paul Gulig (Committee Member)

No Community Members were present for this review. The Community Member that was assigned to this review was unable to attend the meeting. The committee voted unanimously in favor to conduct the review without a Community Member in attendance.

Other Persons Present: [REDACTED]

Conflict of Interest: The IBC Chair queried the IBC to identify any potential conflicts of interest and requested that any potential conflicts of interest be disclosed to the IBC. The IBC Chair then reminded the IBC that if any potential conflicts of interest were identified as the meeting progressed, disclosure would need to occur at that time. Identified potential conflict of interest: Yes No

Study Summary Information for Minutes			
Protocol #	[REDACTED]	IBC Study Submission ID #	PROTO202100181
Study Title	[REDACTED] Study: An Open-label, Dose-escalation and Dose-expansion Study of the Safety and Efficacy of a Single Intrathecal Administration of [REDACTED], an AAV[REDACTED]-Delivered Gene Therapy, in the Treatment of Females with Rett Syndrome		
Agent	Adeno-Associated Virus (AAV)		
Agent Characteristics	Replication deficient vector; Risk Group 1		
rDNA Category	III-C-1		
Description of Recombinant Nucleic Acid Sources	[REDACTED]		

Description of Genetically Modified Microbes or Vectors	Replication-deficient AAV encoding an engineered form human [REDACTED] and [REDACTED]				
Description of Transgene Expression	An engineered form human [REDACTED] cDNA [REDACTED]				
Risk Assessment of Procedures	<ul style="list-style-type: none"> • Preparation of Dose <ul style="list-style-type: none"> ○ Sharps Safety ○ Standard Precautions • Administered intrathecal <ul style="list-style-type: none"> ○ Sharps Safety ○ Standard Precautions • Dispose of all materials as biohazardous waste 				
Site Information					
Site Name	Gillette Children's Specialty Healthcare - St. Paul, MN	IBC Site Submission ID #	SAF202500538		
PI Name	Timothy Feyma				
Site Biosafety Level	BSL2				
Staff Training Verified by PI Signed SOP	<input checked="" type="checkbox"/>	Yes	<input type="checkbox"/>	No	
Motions, Votes, and Committee's Decision					
Motion: Approve					
Conditions: N/A					
Motion	First: [REDACTED]	Second: [REDACTED]			
Votes	For: 7	Against: 0	Recused: 0	Absent: 0	Abstained: 0

Chair Signature

Approved by Chair:

Name: Darlene Ward

Date: 2026/01/15