



Institutional Biosafety Committee
Meeting Minutes

Date: 01/16/2026 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), Warren Rummage (Committee Member), Alain Houmeidan (Committee Member), Jackie Lomeli (Committee Member), Paul Gulig (Committee Member), Kevin Pruitt (Committee Member), Leanne Cobb (Community Member), Eli Lichter (Community Member)

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 #	PROTO202400152
Study Title	A Phase 3, Randomized, Observer-blinded, Placebo-controlled Study to Evaluate the Safety and Efficacy of [REDACTED], a Multivalent Candidate Vaccine to Prevent Norovirus Acute Gastroenteritis in Adults ≥18 Years of Age		
Agent	lipid nanoparticle encapsulated mRNA		
Agent Characteristics	lipid nanoparticle encapsulated mRNA		
rDNA Category	III-C-1		
Description of Recombinant Nucleic Acid Sources	<ul style="list-style-type: none"> • mRNAs encoding [REDACTED]. 		

Description of Genetically Modified Microbes or Vectors	<ul style="list-style-type: none"> N/A 				
Description of Transgene Expression	<ul style="list-style-type: none"> mRNAs encoding [REDACTED]. 				
Risk Assessment of Procedures	<ul style="list-style-type: none"> Delivered intramuscularly <ul style="list-style-type: none"> Sharps Safety Standard Precautions All materials disposed of as biohazardous waste 				
Site Information					
Site Name	DM Clinical Research - Brookline, MA	IBC Site Submission ID #	AMEND202600009		
PI Name	James Katz				
Site Biosafety Level	BSL2				
Staff Training Verified by PI Signed SOP	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No				
Amendment Summary	<ul style="list-style-type: none"> PI Change from Basmah Jalil to James Katz Room Addition 				
Motions, Votes, and Committee's Decision					
Motion: Approve					
Conditions: N/A					
Motion	First: [REDACTED]		Second: [REDACTED]		
Votes	For: 10	Against: 0	Recused: 0	Absent: 0	Abstained: 0

Chair Signature

Approved by Chair:

Name: Darlene Ward

Date: 2026/01/16