



Institutional Biosafety Committee
Meeting Minutes

Date: 11/14/2025 Start time: 3:00pm (ET) End time: 5:00pm (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: Warren Rummage

Voting Members Present: Dan Eisenman (Committee Member), Nichole Tower (Committee Member), Alain Houmeidan (Committee Member), Jackie Lomeli (Committee Member), Scott Swindle (Committee Member), Jenna McKenzie (Committee Member), Paul Gulig (Committee Member), Shivangi Paliwal (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 #	PROTO202400165
Study Title	A Phase 3 Randomized Double-blind Study of Adjuvant Pembrolizumab With or Without [REDACTED] in Participants With Resectable Stage II to IIIB (N2) NSCLC not Achieving pCR After Receiving Neoadjuvant Pembrolizumab With Platinum-based Doublet Chemotherapy [REDACTED]		
Agent	lipid nanoparticle encapsulated mRNA		
Agent Characteristics	lipid nanoparticle encapsulated mRNA		
rDNA Category	III-C-1		
Description of Recombinant Nucleic Acid Sources	• [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"> [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	UCH-MHS d/b/a Memorial Health System - Colorado Springs, CO			IBC Site Submission ID #	AMEND202501395
PI Name	Ann Mellott				
Site Biosafety Level	BSL2				
Staff Training Verified by PI Signed SOP	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No				
Amendment Summary	PI Change from Robert Hoyer to Ann Mellott				
Motions, Votes, and Committee's Decision					
Motion: Approve					
Conditions: N/A					
Motion	First: [REDACTED]		Second: [REDACTED]		
Votes	For: 8	Against: 0	Recused: 0	Absent: 0	Abstained: 0

Chair Signature
Approved by Chair: Name: Warren Rummage Date: 2025/11/20