RUSH

RUSH Institutional Biosafety Committee (IBC)	
Meeting Date	October 22, 2025
Meeting Time	12:00 PM – 1:00 PM
Meeting Type	Virtual via Microsoft Teams
IBC Members Present	1. Amarjit Virdi, Ph.D. (IBC Chair) 2. Ed R. Blazek, Ph.D., SM (NRCM) (BSO) 3. João Mamede, Ph.D. (IBC Member / Recombinant DNA Technologies) 4. Rebecca 'Bex' Ober, D.V.M. (IBC Member / Veterinary Medicine) 5. Jeffrey Oswald, D.V.M., Comparative Research Center (IBC Member / Veterinary Medicine) 6. Liudmila Romanova, Ph.D. (IBC Member / Expertise Neurological Sciences) 7. Adam Roubitchek, Ed.D. (Local Non-Affiliated Member) 8. Jennifer Strong (*ex officio* Non-Voting / Research Compliance) 9. Brett Williams, M.D. (IBC Member / Infectious Disease Physician)
Quorum	Quorum was declared by the Chair. The IBC has eleven voting members, and six members are required to conduct business.
Other Individuals in Attendance	1. Christine VanTubbergen, MPH (Program Manager, Office of Research Affairs)
Call to Order	The IBC Chair called the meeting to order at 12:00 PM.
Conflicts of Interest	The IBC Chair reminded all members present to identify any conflicts of interest as each application is reviewed.
Review and Approval of Previous Meeting Minutes	September 24, 2025 Motion: Approve the minutes as circulated. Votes: 6-0-0-0 (for-against-abstain-recuse)

Review of Prior Business		
PI Name & ORA #	**Application**	**Approval Date**
Deborah Hall, M.D. 24072503-IBC01	Initial Application	Withdrawn 9/26/2025
Sunita Nathan, M.D. 20050801-IBC-35	Amendment 38	9/29/2025
Elizabeth Berry-Kravis, M.D. 24090903-IBC06	Amendment 5	9/30/2025
Mouhamed Kelta, M.D. 24082607-IBC06	Amendment 5	9/30/2025
Deborah Hall, M.D. 19010804-IBC29	Amendment 34	9/30/2025
Elizabeth Berry-Kravis, M.D. 24021304-IBC10	Amendment 8	10/07/2025
Elizabeth Berry-Kravis, M.D. 25032404-IBC02	Amendment 1	10/07/2025
Elizabeth Berry-Kravis, M.D. 24022207-IBC06	Amendment 4	10/9/2025
Peter Reisz, M.D. 23082101-IBC07	Amendment 6	Withdrawn 10/9/2025
Peter Reisz, M.D. 23082101-IBC08	Continuing Review 1	10/9/2025

Rachel Miller, Ph.D. 19050702-IBC01	Continuing Review 1	10/10/2025
Elizabeth Berry-Kravis, M.D. 23071701-IBC01	All Applications	Closed 10/16/2025
Lean Al-Harthi, Ph.D. 17092503-IBC03	All Applications	Closed 10/16/2025
Thomas Westbrook, M.D. 24032202-IBC05	Amendment 4	10/20/2025
Adrienn Markovics, M.D., Ph.D. 24071903-IBC03	Amendment 2	10/20/25

New IBC Applications for Review	
PI Name	Mindy Simpson, M.D.
ORA#	23110201-IBC01
Project Overview	**III-C-1** This is a Phase 1/2, two-part open-label study designed to determine a safe and well-tolerated dose of a CRISPR/Cas9-based coagulation Factor IX gene insertion therapy (REGV131-LNP1265) for the treatment of adult, adolescent, and pediatric patients with moderately severe congenital hemophilia B. The capsid of REGV131 is derived from adeno-associated virus serotype 8 (AAV8) and contains a single-stranded DNA template encoding wild-type human coagulation Factor IX. LNP1265 is a lipid nanoparticle encapsulating a Cas9 mRNA and single guide RNA. The trial is sponsored by Regeneron Pharmaceuticals (ClinicalTrials.gov ID: NCT06379789). Participants will receive a single dose of REGV131-LNP1265. Part 1 of the study will consist of dose escalation and dose confirmation in adult patients. Part 2 will consist of dose expansion of the recommended dose for expansion (RDE), as determined in Part 1. Adolescent and pediatric patients will receive a weight-adjusted RDE.
NIH Guidelines Section	**III-C-1**
Risk Assessment & Discussion	• Adeno-associated virus is a RG-1 agent. • The study drug will be prepared within a biological safety cabinet (BSC). • PPE consisting of disposable rear-closing gown, gloves, surgical mask, face shield, shoe covers, and eye protection will be utilized when preparing or administering the agent. • Materials that come into contact with the agent will be disposed of as biohazardous waste. • Risks to participants described in the informed consent form (ICF) should be made to be consistent with those of other, related gene therapies. Liver risks (associated with other AAV8 gene therapies) and systemic risks (such as severe inflammatory responses and 1 case of death, associated with other AAV gene therapies) should be described.
Training	For research requiring IBC oversight, the PI must complete the CITI Initial Biosafety Training course and clinical lab personnel must complete the CITI Basic Biosafety Training course. For research involving human gene transfer, the PI and personnel must complete either the CITI Recombinant Clinical Biosafety Course or the CITI Recombinant Clinical Coordinator course, depending on research activity involvement.

	At least one individual has current CITI International Air and Transportation Association (IATA) training.
Occupational Health Representative Review (if applicable)	Not applicable.
BSL Assignment	• BSL-1

IBC Vote	• A motion was made to provisionally approve this application pending the following conditions are met:
	  • Completion of biosafety training for all personnel
	  • Addition of BSC information to the application
	  • Addition of waste disposal methods to application
	  • Addition of liver and systemic risks to the ICF
	  • Removal of the language 'modified to be harmless' from the ICF
	Votes:
	• 7-0-1-0
	Conflicts of Interest: None

New IBC Applications for Review	
PI Name	Ira Miller, M.D., Ph.D.
ORA#	22070504-IBC02
Project Overview	**III-E-1** This study aims to develop a biological therapeutic for B cell lymphoma that induces complement-dependent cytotoxicity. Antibody constructs directed towards surface membrane proteins will be utilized.
NIH Guidelines Section	**III-E-1**
Risk Assessment & Discussion	• A biological safety cabinet (BSC) will be utilized. • PPE consisting of lab coat and gloves will be utilized. • Waste disposal methods were not described within the application.
Training	For research requiring IBC oversight, the PI must complete the CITI Initial Biosafety Training course and clinical lab personnel must complete the CITI Basic Biosafety Training course. For research involving human gene transfer, the PI and personnel must complete either the CITI Recombinant Clinical Biosafety Course or the CITI Recombinant Clinical Coordinator course, depending on research activity involvement. At least one individual has current CITI International Air and Transportation Association (IATA) training.
Occupational Health Representative Review (if applicable)	Not applicable.
BSL Assignment	• BSL-2
IBC Vote	• A motion was made to table this application, requesting more information and clarification on the study regarding specific experiments, experimental measurements, personnel experience, etc. Votes: • 8-0-0-0 Conflicts of Interest: None

New Business	uniQure Announces Positive Topline Results from Pivotal Phase I/II Study of AMT-130 in Patients with Huntington's Disease • https://uniqure.gcs-web.com/news-releases/news-release-details/uniqure-announces-positive-topline-results-pivotal-phase-iii
Review of Incidents	Nothing to report.
Inspections/Ongoing Oversight	Nothing to report.
IBC Training	Nobel Prize in Physiology or Medicine 2025 • https://www.nobelprize.org/prizes/medicine/2025/press-release/
Public Comments	There were no public comments.
Adjournment	The IBC Chair moved to adjourn the meeting at 1:03 PM The next meeting scheduled is for November 19, 2025 at 12:00 PM via Microsoft Teams.