RUSH

RUSH Institutional Biosafety Committee (IBC)	
Meeting Date	October 28, 2026
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. Liudmila Romanova, Ph.D. (IBC Member / Expertise Neurological Sciences) 5. Jennifer Strong (*ex officio* Non-Voting / Research Compliance) 6. Brett Williams, M.D. (IBC Member / Infectious Disease Physician)
Quorum	Quorum was declared by the Chair. The IBC has nine voting members, and five members are required to conduct business.
Other Individuals in Attendance	1. Christine VanTubbergen, MPH (Program Manager, Office of Research Affairs)
Call to Order	The Chair called the meeting to order at 12:00 PM.
Conflicts of Interest	The Chair reminded all members present to identify any conflicts of interest as each application is reviewed.
Review and Approval of Previous Meeting Minutes	September 23, 2026 Motion: Approve the minutes as circulated. Votes: 5-0-0-0 (for-against-abstain-recuse)

Review of Prior Business		
PI Name & ORA #	**Application**	**Approval Date**
Asimakopoulos, Fotios, M.D. 25040806-IBC02	Amendment 01	10/27/26
Nathan, Sunita, M.D. 19070910-IBC28	Continuing Review 01	10/27/26
Asimakopoulos, Fotios, M.D. 23081106-IBC15	Amendment 11	10/22/26
Nathan, Sunita, M.D. 21060306-IBC31	Amendment 27	10/12/26
Patel, Neepa, M.D. 23091102-IBC10	Amendment 08	10/06/26
Nathan, Sunita, M.D. 24061205-IBC12	Amendment 11	10/02/26
Predescu, Sanda, Ph.D. 15090702-IBC06	Renewal Application	10/02/26
Kirby, Alana, M.D., Ph.D. 26031201-IBC01	Initial Application	10/02/26
Berry-Kravis, Elizabeth, M.D. 25032404-IBC06	Amendment 03	09/29/26
Hall, Deborah, M.D. 19010804-IBC33	Amendment 37	09/23/26

New IBC Applications for Review	
PI Name	Pratap, Jitesh, Ph.D.
ORA#	23072005-IBC03
Project Overview	**III-D-4** **III-F-1** This study will utilize a mouse model to investigate the role of tubulin proteins in bone metastatic breast cancer.
NIH Guidelines Section	**III-D-4** **III-F-1**
Risk Assessment & Discussion	• Lentivirus is an RG-2 agent. Replication-defective vectors will be utilized. • Bacterial plasmids are an RG-1 agent. • Small interfering RNA (siRNA) will be utilized. • Synthetic nucleic acids will be utilized. • CRISPR/Cas9 will be utilized. • A certified biological safety cabinet (BSC) will be utilized. • PPE consisting of lab coat, gloves, surgical mask, and eye protection will be utilized.
Training	For nonclinical research requiring IBC oversight, the PI must complete the CITI Initial Biosafety Training course and 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, if any biohazardous materials will be shipped.
Occupational Health Representative Review (if applicable)	Not applicable.
BSL Assignment	• BSL-2

IBC Vote	• A motion was made to provisionally approve this application pending the following conditions be met:
	  • Upload signed core facility affidavits.
	  • Upload biosafety training certificates for all listed personnel.
	  • Assignment of risk categories for infectious agents.
	  • Addition of laboratory rules.
	  • Corrections to vector names and terminology.
	Votes:
	• 5-0-0-0
	Conflicts of Interest: None.

New IBC Applications for Review	
PI Name	Block, Joel, M.D.
ORA#	25111005-IBC01
Project Overview	**III-C-1** This is randomized, placebo-controlled, multisite, two-part Phase II, study evaluating the safety and tolerability of different doses of PCRX-201, following steroid pretreatment, in patients 45-80 years of age with painful osteoarthritis of the knee. PCRX-201 (enekinragene inzadenovec) is an adenoviral vector gene therapy that is locally injected in the knee joint and is intended to reduce chronic inflammation by promoting receptor antagonist (IL-Ra) production and blocking IL-1 pathway activation. This trial is

	sponsored by Pacira Pharmaceuticals, Inc. (ClinicalTrials.gov ID: NCT06884865).
NIH Guidelines Section	**III-C-1**
Risk Assessment & Discussion	• Adenovirus is an RG-2 agent. • A certified biological safety cabinet (BSC) will be utilized. • PPE consisting of lab coat, gloves, and surgical mask will be utilized.
Training	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, if any biohazardous materials will be shipped.
Occupational Health Representative Review (if applicable)	Not applicable.
BSL Assignment	• BSL-2

IBC Vote	• A motion was made to provisionally approve this application pending the following conditions be met:
	  • Upload biosafety training certificates for all listed personnel.
	  • Assignment of risk category for infectious agent.
	  • Addition of BSC information.
	  • Addition of non-commercial vector name.
	  • Correction to the informed consent form regarding description of vector and risk of integration.
	  • Addition of waste disposal methods.
	Votes:
	• 5-0-0-0
	Conflicts of Interest: None.

New IBC Applications for Review	
PI Name	Berry-Kravis, Elizabeth, M.D.
ORA#	26080901-IBC01
Project Overview	**III-C-1** This is a single-patient expanded access program for a pediatric patient with Rett syndrome. RTT-1 is a mRNA lipid nanoparticle protein replacement therapy delivered by intravenous infusion.
NIH Guidelines Section	**III-C-1**
Risk Assessment & Discussion	• This project will not utilize an infectious agent. • A certified biological safety cabinet (BSC) will be utilized. • PPE consisting of lab coat, reusable rear-closing gown, disposable rear-closing gown, gloves, and eye protection will be utilized.
Training	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, if any biohazardous materials will be shipped.
Occupational Health Representative Review (if applicable)	Not applicable.
BSL Assignment	• BSL-1
IBC Vote	• A motion was made to approve this application as submitted. Votes:

	• 5-0-0-0 Conflicts of Interest: None.

New Business	a. NIH Releases Draft Biosafety Policy for Research Involving Biohazards for Public Comment, 08/19/26 https://grants.nih.gov/grants/guide/notice-files/NOT-OD-26-112.html Committee members were informed that the IBC Subcommittee submitted a comment on the draft policy.
Review of Incidents	Nothing to report.
Inspections/Ongoing Oversight	Nothing to report.
IBC Training	Nothing to report.
Public Comments	There were no public comments.
Adjournment	The Chair moved to adjourn the meeting at 12:52 PM The next meeting scheduled is for November 18, 2026 at 12:00 PM via Microsoft Teams.