

RUSH Institutional Biosafety Committee (IBC)	
Meeting Date	March 25, 2026
Meeting Time	12:00 PM – 1:00 PM
Meeting Type	Virtual via Microsoft Teams
IBC Members Present	<ol style="list-style-type: none"> 1. Ed R. Blazek, Ph.D., SM (NRCM) (BSO) 2. João Mamede, Ph.D. (IBC Member / Recombinant DNA Technologies) 3. Rebecca ‘Bex’ Ober, D.V.M. (Senior Director, Comparative Research Center) 4. Liudmila Romanova, Ph.D. (IBC Member / Expertise Neurological Sciences) 5. Adam Roubitchek, Ed.D. (Local Non-Affiliated Member) 6. Jennifer Strong (<i>ex officio</i> Non-Voting / Research Compliance) 7. Derrick Swistak (Non-Affiliated Member) 8. Brett Williams, M.D. (IBC Member / Infectious Disease Physician)
Quorum	<p>Quorum was declared by the BSO.</p> <p>The IBC has nine voting members, and five members are required to conduct business.</p>
Other Individuals in Attendance	<ol style="list-style-type: none"> 1. Christine VanTubbergen, MPH (Program Manager, Office of Research Affairs)
Call to Order	The BSO called the meeting to order at 12:01 PM.
Conflicts of Interest	The BSO reminded all members present to identify any conflicts of interest as each application is reviewed.
Review and Approval of Previous Meeting Minutes	<p>February 25, 2026</p> <p>Motion: Approve the minutes as circulated.</p> <p>Votes: 6-0-0-0 (for-against-abstain-recuse)</p>

Review of Prior Business		
PI Name & ORA #	Application	Approval Date
Nathan, Sunita, M.D. 21060306-IBC26	Amendment 23	2/25/2026
Patel, Neepa, M.D. 23091102-IBC06	Amendment 05	3/3/2026
Patel, Neepa, M.D. 23091102-IBC06	Amendment 05	3/4/2026
Westbrook, Thomas, M.D. 24032202-IBC08	Amendment 06	3/12/2026
Berry-Kravis, Elizabeth, M.D. 24021304-IBC13		Withdrawn 3/17/2026
Berry-Kravis, Elizabeth, M.D. 24021304-IBC14	Continuing Review 02	3/17/2026
Berry-Kravis, Elizabeth, M.D. 21070805-IBC04	Amendment 03	3/20/2026
Berry-Kravis, Elizabeth, M.D. 21070805-IBC04	Amendment 03	3/20/2026

New IBC Applications for Review	
PI Name	Berry-Kravis, Elizabeth, M.D.
ORA#	26013003-IBC01
Project Overview	<p>III-C-1</p> <p>This is an EAP (expanded access program) for neuronal ceroid lipofuscinosis (CLN1 disease), also referred to as juvenile Batten’s disease.</p>

	TSHA-118 is a self-complementary adeno-associated virus serotype 9 (AAV9) gene replacement therapy designed to express a human codon-optimized CLN1 transgene for the treatment of CLN1 disease.
NIH Guidelines Section	III-C-1
Risk Assessment & Discussion	<ul style="list-style-type: none"> • Adeno-associated virus (AAV) is a RG-1 agent. • A biological safety cabinet (BSC) will be utilized. • PPE consisting of reusable rear-closing gown, gloves, surgical mask, head cover, and eye protection will be utilized. • All injection materials will be sealed in leak-proof primary and secondary biohazard bags. • Needles will be disposed of in biohazard sharps waste container. • All other waste will be double-bagged in biohazard bags and disposed of in a biohazard waste container.
Training	<p>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.</p> <p>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.</p> <p>At least one individual has current CITI International Air and Transportation Association (IATA) training, if any biohazardous materials will be shipped.</p>
Occupational Health Representative Review (if applicable)	Not applicable.
BSL Assignment	<ul style="list-style-type: none"> • BSL-1
IBC Vote	<ul style="list-style-type: none"> • A motion was made to provisionally approve this application pending the following conditions be met: <ul style="list-style-type: none"> • Addition of AAV-specific risk of death language to ICF <p><u>Votes:</u></p> <ul style="list-style-type: none"> • 7-0-0-0 <p>Conflicts of Interest: None.</p>

New IBC Applications for Review	
PI Name	Osen, Allison, M.D.
ORA#	25111404-IBC01
Project Overview	<p>III-C-1</p> <p>This is a Phase 1 study to evaluate the safety and clinical activity of azercabtagene zapreleucel (azer-cel) in participants with B-cell mediated autoimmune disorders, such as progressive forms of multiple sclerosis. Participants will receive a single intravenous infusion of azer-cel.</p> <p>Azer-cel is an anti-CD19 chimeric antigen receptor (CAR) T-cell therapy. Azer-cel is allogenic and derived from healthy donor T cells which have been modified to express a CD19-directed CAR and intended to reduce the risk of graft-versus-host disease. The trial is sponsored by TG Therapeutics, Inc. (ClinicalTrials.gov ID: NCT06680037).</p>
NIH Guidelines Section	III-C-1
Risk Assessment & Discussion	<ul style="list-style-type: none"> • This project will not utilize an infectious agent. • A biological safety cabinet (BSC) will be utilized. • PPE consisting of lab coat and gloves will be utilized. • Waste will be disposed of as biohazard waste.
Training	For nonclinical research requiring IBC oversight, the PI must complete the CITI Initial

	<p>Biosafety Training course and lab personnel must complete the CITI Basic Biosafety Training course.</p> <p>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.</p> <p>At least one individual has current CITI International Air and Transportation Association (IATA) training, if any biohazardous materials will be shipped.</p>
Occupational Health Representative Review (if applicable)	Not applicable.
BSL Assignment	<ul style="list-style-type: none"> • BSL-2
IBC Vote	<ul style="list-style-type: none"> • A motion was made to provisionally approve this application pending the following condition be met: <ul style="list-style-type: none"> • Provision from sponsor of human safety data from previous study of azer-cel for lymphoma • Clarify usage of BSC <p><u>Votes:</u></p> <ul style="list-style-type: none"> • 7-0-0-0 <p>Conflicts of Interest: None</p>

New Business	Nothing to report.
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	<p>The BSO moved to adjourn the meeting at 12:49 PM</p> <p>The next meeting scheduled is for April 22, 2026 at 12:00 PM via Microsoft Teams.</p>