



RUSH Institutional Biosafety Committee (IBC)	
Meeting Date	February 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. Amarjit Viridi, 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. (Senior Director, Comparative Research Center) 5. Liudmila Romanova, Ph.D. (IBC Member / Expertise Neurological Sciences) 6. Adam Roubitchek, Ed.D. (Local Non-Affiliated Member) 7. Brett Williams, M.D. (IBC Member / Infectious Disease Physician)
Quorum	<p>Quorum was declared by the Chair.</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 IBC Chair called the meeting to order at 12:01 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	<p>January 21, 2026</p> <p>Motion: Approve the minutes as circulated, with one minor correction.</p> <p>Votes: 5-0-1-0 (for-against-abstain-recuse)</p>

Review of Prior Business		
PI Name & ORA #	Application	Approval Date
Berry-Kravis, Elizabeth, M.D. 23092006-IBC17		Withdrawn 1/22/2026
Berry-Kravis, Elizabeth, M.D. 21070805-IBC02	Amendment 01	1/22/2026
Jain, Shivi, M.D. 24082607-IBC07		Withdrawn 1/23/2026
Kelta, Mouhammed, M.D. 23081106-IBC09	Amendment 07	1/24/2026
Nathan, Sunita, M.D. 19070910-IBC23	Amendment 21	1/24/2026
Nathan, Sunita, M.D. 21070206-IBC23	Amendment 16	1/24/2026
Nathan, Sunita, M.D. 21060306-IBC25	Amendment 22	1/24/2026
Jain, Shivi, M.D. 24082607-IBC08		Withdrawn 1/26/26
Nathan, Sunita, M.D. 24061205-IBC09	Amendment 07	2/2/2026
Steinberg, Gary, M.D. 25041701-IBC01	Initial Application	Closed 2/10/2026
Steinberg, Gary, M.D. 25030502-IBC01	Initial Application	Closed 2/10/2026
Hall, Deborah, M.D. 19010804-IBC31	Continuing Review 06	2/17/2026
Berry-Kravis, Elizabeth, M.D. 21070805-IBC03	Amendment 02	2/17/2026

Jain, Shivi, M.D. 24082607-IBC10	Continuing Review 02	2/17/2026
Nathan, Sunita, M.D. 21060306-IBC26	Amendment 23	2/18/2026
Berry-Kravis, Elizabeth, M.D. 24042305-IBC 11	Amendment 09	2/17/2026

New IBC Applications for Review	
PI Name	Rubenstein, Jonathan, M.D.
ORA#	25100705-IBC01
Project Overview	<p>III-C-1 III-D-3</p> <p>This is a Phase 1/2, randomized, double-masked, multicenter, placebo-controlled clinical trial evaluating the safety, tolerability, and preliminary efficacy of KB801, administered as an eye drop, for the treatment of neurotrophic keratitis in adults with Stage 2 or Stage 3 of the disease.</p> <p>KB801 is a redosable eye drop gene therapy designed to enable sustained, localized expression and secretion of nerve growth factor (NGF) by epithelial cells in the front of the eye for the treatment of neurotrophic keratitis, a rare, degenerative corneal disease that leads to corneal epithelial defects, ulcers, and perforation. KB801 is a replication-defective, non-integrating herpes simplex virus type 1 (HSV-1)-derived vector engineered to deliver functional full-length NGF. The trial is sponsored by Krystal Biotech, Inc. (ClinicalTrials.gov ID: NCT06999733).</p>
NIH Guidelines Section	III-C-1 III-D-3
Risk Assessment & Discussion	<ul style="list-style-type: none"> • The HSV-1 vector is a RG-2 agent and containment level should be considered BSL-2. • A biological safety cabinet (BSC) will be utilized. • PPE consisting of lab coat, gloves, disposable rear-closing gown, and eye protection will be utilized. • Surfaces that come into contact with KB801 and spills of KB801 should be disinfected with bleach or 70% ethanol. • All materials that come into contact with KB801 will be disposed of as biohazardous waste. Study participants will be supplied with a biohazard waste container that can be shipped back or returned to the study site for disposal.
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-2
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"> • Use of current Rush template for ICF • Removal of “anticipated there will be no risk of infection” statement from ICF

	<ul style="list-style-type: none"> Removal of “if you receive placebo, your eye condition may worsen” statement from ICF Updating risk category to BSL-2 <p><u>Votes:</u></p> <ul style="list-style-type: none"> 7-0-0-0 <p>Conflicts of Interest: None.</p>
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New IBC Applications for Review	
PI Name	Berry-Kravis, Elizabeth, M.D.
ORA#	26020605-IBC01
Project Overview	<p>III-C-1 This is a Phase 2b/3 study of the safety, tolerability, and preliminary efficacy of TSHA-102 in females aged 2-4 years with typical Rett syndrome, with a documented pathogenic mutation of the MECP2 gene that results in loss of gene function. Participants will receive a single intrathecal administration of high dose TSHA-102 scaled to account for the lower brain volume in 2-4 year olds. Data from participants of this age group are being added to the trial for inclusion in the planned Biologics License Application submission to enable broad labeling of TSHA-102 for patients aged ≥ 2 years with Rett syndrome.</p> <p>TSHA-102 is a self-complementary intrathecally delivered AAV9 investigational gene transfer therapy in clinical evaluation for Rett syndrome. Designed as a one-time treatment, TSHA-102 aims to address the genetic root cause of the disease by delivering a functional form of MECP2 to cells in the CNS. TSHA-102 utilizes a novel miRNA-Responsive Auto-Regulatory Element (miRARE) technology designed to mediate levels of MECP2 in the CNS on a cell-by-cell basis without risk of overexpression. The trial is sponsored by Taysha Gene Therapies, Inc. (ClinicalTrials.gov ID: NCT05606614).</p>
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 disposable rear-closing gown, gloves, surgical mask, eye protection, and head cover will be utilized. All infusion 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 condition be met: <ul style="list-style-type: none"> Use of current Rush template for ICF <p><u>Votes:</u></p> <ul style="list-style-type: none"> 7-0-0-0

	Conflicts of Interest: None
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New Business	Nothing to report.
Review of Incidents	Nothing to report.
Inspections/Ongoing Oversight	Nothing to report.
IBC Training	<p>A committee member called attention to the following recent publication that purports to explain a rare but serious toxicity associated with adenoviral gene therapy and some adenoviral infections.</p> <ul style="list-style-type: none"> Wang, J. J., Schönborn, L., Warkentin, T. E., Müller, L., Thiele, T., Ulm, L., Völker, U., Ameling, S., Franzenburg, S., Kaderali, L., Tzvetkova, A., Colella, A., Chataway, T., Tan, C. W., Armour, B., Troelnikov, A., Rutten, L., McCluskey, J., Zahn, R., Gordon, T. P., ... Greinacher, A. (2026). Adenoviral Inciting Antigen and Somatic Hypermutation in VITT. <i>The New England Journal of Medicine</i>, 394(7), 669–683. https://doi.org/10.1056/NEJMoa2514824 <p>The sixth and final Strengthening and Modernizing Biosafety Oversight listening session will occur on February 26, 2026.</p> <ul style="list-style-type: none"> https://osp.od.nih.gov/events/strengthening-and-modernizing-biosafety-oversight-region-6-listening-session/
Public Comments	There were no public comments.
Adjournment	The IBC Chair moved to adjourn the meeting at 12:58 PM The next meeting scheduled is for March 25, 2026 at 12:00 PM via Microsoft Teams.