

<b>RUSH Institutional Biosafety Committee (IBC)</b>	
<b>Meeting Date</b>	April 22, 2026
<b>Meeting Time</b>	12:00 PM – 1:00 PM
<b>Meeting Type</b>	Virtual via Microsoft Teams
<b>IBC Members Present</b>	<ol style="list-style-type: none"> <li>1. Amarjit Viridi, Ph.D. (IBC Chair)</li> <li>2. Ed R. Blazek, Ph.D., SM (NRCM) (BSO)</li> <li>3. João Mamede, Ph.D. (IBC Member / Recombinant DNA Technologies)</li> <li>4. Liudmila Romanova, Ph.D. (IBC Member / Expertise Neurological Sciences)</li> <li>5. Adam Roubitchek, Ed.D. (Local Non-Affiliated Member)</li> <li>6. Jennifer Strong (<i>ex officio</i> Non-Voting / Research Compliance)</li> <li>7. Derrick Swistak (Non-Affiliated Member)</li> <li>8. Brett Williams, M.D. (IBC Member / Infectious Disease Physician)</li> </ol>
<b>Quorum</b>	<p>Quorum was declared by the Chair.</p> <p>The IBC has nine voting members, and five members are required to conduct business.</p>
<b>Other Individuals in Attendance</b>	<ol style="list-style-type: none"> <li>1. Christine VanTubbergen, MPH (Program Manager, Office of Research Affairs)</li> </ol>
<b>Call to Order</b>	The Chair called the meeting to order at 12:02 PM.
<b>Conflicts of Interest</b>	The Chair reminded all members present to identify any conflicts of interest as each application is reviewed.
<b>Review and Approval of Previous Meeting Minutes</b>	<p>March 25, 2026</p> <p>Motion: Approve the minutes as circulated.</p> <p>Votes: 4-0-1-0 (for-against-abstain-recuse)</p>

<b>Review of Prior Business</b>		
<b>PI Name &amp; ORA #</b>	<b>Application</b>	<b>Approval Date</b>
Nathan, Sunita, M.D. 21060306-IBC26	Amendment 23	3/27/2026
Mamede, João, Ph.D. 22071201-IBC02	Amendment 01	3/27/2026
Rubenstein, Jonathan, M.D. 25100705-IBC01	Initial Application	3/27/2026
Nathan, Sunita, M.D. 21060306-IBC27	Continuing Review 05	3/27/2026
Asimakopoulos, Fotios, M.D. 23081106-IBC10	Amendment 08	4/2/2026
Osen, Allison, M.D. 25111404-IBC01	Initial Application	4/6/2026
Berry-Kravis, Elizabeth, M.D. 26020605-IBC01	Initial Application	4/14/2026
Nathan, Sunita, M.D. 24061205-IBC10	Amendment 09	4/15/2026
Baranwal, Anmol, M.D. 21070206-IBC24	Amendment 17	4/15/2026
Malfait, Anne-Marie, Ph.D. 12052504-IBC04	Amendment 01	4/21/2026
Berry-Kravis, Elizabeth, M.D. 21070805-IBC05	Amendment 04	4/22/2026

<b>New IBC Applications for Review</b>	
<b>PI Name</b>	Killinger, Bryan, Ph.D.
<b>ORA#</b>	25011701-IBC01
<b>Project Overview</b>	<b>III-D-4</b> This study will transduce mice with AAV2 vectors containing wild type or mutant mouse alpha-synuclein.
<b>NIH Guidelines Section</b>	<b>III-D-4</b>
<b>Risk Assessment &amp; Discussion</b>	<ul style="list-style-type: none"> <li>• Adeno-associated virus (AAV) is a RG-1 agent.</li> <li>• A biological safety cabinet (BSC) will be utilized.</li> <li>• PPE consisting of reusable rear-closing gown, gloves, surgical mask, full face shield, head cover, and shoe covers will be utilized.</li> </ul>
<b>Training</b>	<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>
<b>Occupational Health Representative Review (if applicable)</b>	Not applicable.
<b>BSL Assignment</b>	<ul style="list-style-type: none"> <li>• BSL-1</li> </ul>
<b>IBC Vote</b>	<ul style="list-style-type: none"> <li>• A motion was made to provisionally approve this application pending the following conditions be met: <ul style="list-style-type: none"> <li>• Upgrading containment level to BSL-2 for laboratory work and injections, post-injection animal work can be performed at BSL-1-N</li> <li>• Description of waste disposal methods</li> <li>• Description of where vector work will be conducted</li> <li>• Addition of virus/vector experience to personal training descriptions</li> </ul> </li> </ul> <p><u>Votes:</u></p> <ul style="list-style-type: none"> <li>• 7-0-0-0</li> </ul> <p>Conflicts of Interest: None.</p>

<b>New IBC Applications for Review</b>	
<b>PI Name</b>	Asimakopoulos, Fotios, M.D.
<b>ORA#</b>	25040806-IBC01
<b>Project Overview</b>	<p><b>III-C-1</b></p> <p>This is a randomized, multicenter, controlled, open-label, Phase III global study comparing the efficacy and safety of AZD0120 versus standard regimens in subjects with relapsed refractory multiple myeloma.</p> <p>AZD0120 is a dual-targeting autologous chimeric antigen receptor t-cell (CAR-T) therapy directed against B-cell maturation antigen (BCMA) and CD19. This trial is sponsored by AstraZeneca (ClinicalTrials.gov ID: NCT07391657).</p>
<b>NIH Guidelines Section</b>	<b>III-C-1</b>
<b>Risk Assessment &amp; Discussion</b>	<ul style="list-style-type: none"> <li>• This project will not utilize an infectious agent.</li> <li>• A biological safety cabinet (BSC) will be utilized.</li> <li>• PPE consisting of lab coat and gloves will be utilized.</li> <li>• Waste will be disposed of as biohazard waste.</li> </ul>
<b>Training</b>	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

	<p>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>
<b>Occupational Health Representative Review (if applicable)</b>	Not applicable.
<b>BSL Assignment</b>	<ul style="list-style-type: none"> <li>• BSL-1</li> </ul>
<b>IBC Vote</b>	<ul style="list-style-type: none"> <li>• A motion was made to approve this application.</li> </ul> <p><u>Votes:</u></p> <ul style="list-style-type: none"> <li>• 7-0-0-0</li> </ul> <p>Conflicts of Interest: None</p>

<b>New IBC Applications for Review</b>	
<b>PI Name</b>	Asimakopoulos, Fotios, M.D.
<b>ORA#</b>	25111204-IBC01
<b>Project Overview</b>	<p><b>III-C-1</b></p> <p>This is a randomized, multicenter, controlled, open-label, Phase III global study comparing the efficacy and safety of AZD0120 compared with continuous standard therapy in subjects with newly diagnosed multiple myeloma and who are ineligible to receive autologous stem cell transplant (ASCT).</p> <p>AZD0120 is a dual-targeting autologous chimeric antigen receptor t-cell (CAR-T) therapy directed against BCMA and CD19. This trial is sponsored by AstraZeneca.</p>
<b>NIH Guidelines Section</b>	<b>III-C-1</b>
<b>Risk Assessment &amp; Discussion</b>	<ul style="list-style-type: none"> <li>• This project will not utilize an infectious agent.</li> <li>• A biological safety cabinet (BSC) will be utilized.</li> <li>• PPE consisting of lab coat and gloves will be utilized.</li> <li>• Waste will be disposed of as biohazard waste.</li> </ul>
<b>Training</b>	<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>
<b>Occupational Health Representative Review (if applicable)</b>	Not applicable.
<b>BSL Assignment</b>	<ul style="list-style-type: none"> <li>• BSL-1</li> </ul>
<b>IBC Vote</b>	<ul style="list-style-type: none"> <li>• A motion was made to approve this application.</li> </ul> <p><u>Votes:</u></p> <ul style="list-style-type: none"> <li>• 7-0-0-0</li> </ul> <p>Conflicts of Interest: None</p>

<b>New Business</b>	Nothing to report.
<b>Review of Incidents</b>	Nothing to report.
<b>Inspections/Ongoing Oversight</b>	Nothing to report.
<b>IBC Training</b>	FDA Approves First Gene Therapy for Severe Leukocyte Adhesion Deficiency Type I <a href="https://www.fda.gov/news-events/press-announcements/fda-approves-first-gene-therapy-severe-leukocyte-adhesion-deficiency-type-i">https://www.fda.gov/news-events/press-announcements/fda-approves-first-gene-therapy-severe-leukocyte-adhesion-deficiency-type-i</a>
<b>Public Comments</b>	There were no public comments.
<b>Adjournment</b>	The Chair moved to adjourn the meeting at 12:55 PM The next meeting scheduled is for May 27, 2026 at 12:00 PM via Microsoft Teams.