RUSH

| RUSH Institutional Biosafety Committee (IBC) | |
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| **Meeting Date** | September 24, 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)<br>2. Ed R. Blazek, Ph.D., SM (NRCM) (BSO)<br>3. João Mamede, Ph.D. (IBC Member / Recombinant DNA Technologies)<br>4. Jeffrey Oswald, D.V.M., Comparative Research Center (IBC Member / Veterinary Medicine)<br>5. Liudmila Romanova, Ph.D. (IBC Member / Expertise Neurological Sciences)<br>6. Jennifer Strong (*ex officio* Non-Voting / Research Compliance)<br>7. Derrick Swistak (Non-Affiliated Member)<br>8. Brett Williams, M.D. (IBC Member / Infectious Disease Physician) |
| **Quorum** | Quorum was declared by the Chair.<br>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 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** | July 30, 2025<br>Motion: Approve the minutes as circulated.<br>Votes: 6-0-1-0 (for-against-abstain-recuse) |

| **Review of Prior Business** | | |
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| **PI Name & ORA #** | **Application** | **Approval Date** |
| Lena Al-Harthi, Ph.D.<br>17111308-IBC01 - 03 | All Applications | Closed 8/5/25 |
| Kalipada Pahan, Ph.D.<br>19073101-IBC01 - 02 | All Applications | Closed 8/5/25 |
| Kwi Hye Koh, Ph.D.<br>21040603-IBC01 | All Applications | Closed 8/5/25 |
| Jochen Reiser, Ph.D.<br>22051103-IBC01 | All Applications | Closed 8/5/25 |
| Gary Steinberg, M.D.<br>25041701-IBC01 | New Application | 8/14/25 |
| Deborah Hall. M.D.<br>19010804-IBC28 | Amendment 33 | 8/5/25 |
| Elizabeth Berry-Kravis, M.D.<br>24021304-IBC08 | Amendment 6 | 8/12/25 |
| Sunita Nathan, M.D.<br>21070206-IBC21 | Amendment 14 | 8/14/25 |
| Mouhammed Kelta, M.D.<br>23081106-IBC07 | Amendment 6 | 8/18/25 |
| Peter Reisz, M.D.<br>23082101-IBC07 | Amendment 6 | 8/20/25 |
| Elizabeth Berry-Kravis, M.D.<br>21070805-IBC01 | New Application | 8/25/25 |

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| Elizabeth Berry-Kravis, M.D.<br>25032404-IBC01 | New Application | 8/25/25 |
| Sunita Nathan, M.D.<br>20050801-IBC34 | Amendment 37 | 8/25/25 |
| Patel, Neepa, M.D.<br>23091102-IBC03 | Amendment 2 | 8/27/25 |
| Sunita Nathan, M.D.<br>24061205-IBC05 | Amendment 4 | 8/29/25 |
| Westbrook, Thomas, M.D.<br>24032202-IBC04 | Amendment 3 | 9/10/25 |
| Elizabeth Berry-Kravis, M.D.<br>24021304-IBC09 | Amendment 7 | 9/11/25 |
| Elizabeth Berry-Kravis, M.D.<br>24090903-IBC05 | Amendment 4 | 9/12/25 |
| Elizabeth Berry-Kravis, M.D.<br>23092006-IBC16 | Continuing Review 2 | 9/12/25 |
| Elizabeth Berry-Kravis, M.D.<br>24061205-IBC06 | Amendment 5 | 9/22/25 |
| Mouhamed Kelta, M.D.<br>24082607-IBC06 | Amendment 5 | 9/23/25 |
| Elizabeth Berry-Kravis, M.D.<br>24090903-IBC06 | Amendment 5 | 9/23/25 |
| Patel, Neepa, M.D.<br>23091102-IBC04 | Amendment 3 | 9/24/25 |

| **New IBC Applications for Review** | |
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| **PI Name** | Steinberg, Gary, M.D. |
| **ORA#** | 25030502-IBC01 |
| **Project Overview** | **III-C-1** This is a single-arm, open-label, multicenter Phase II clinical trial designed to evaluate the tolerability, safety, and preliminary efficacy of MVR-T3011 delivered intravesically into the bladder of adult subjects with Bacillus Calmette Guerin (BCG)-unresponsive high-risk non-muscle-invasive bladder cancer (NMIBC) or BCG-exposed, chemotherapy-unresponsive intermediate/high-risk NMIBC. MVR-T3011 is a novel oncolytic immunotherapy combining a proprietary replication competent oncolytic virus backbone with payload expression of PD-1 antibody and IL-12. Upon delivery, locally produced IL-12 induces IFN-γ production, enhances oncolytic activity of NK cells and cytotoxic T lymphocytes, promotes anti-angiogenesis and inhibits tumor growth. Simultaneously, the PD-1 antibody acts as an immune checkpoint inhibitor to augment T-cell tumor-killing activity. This trial is sponsored by ImmVira Pharmo Co. Ltd. (ClinicalTrials.gov ID: NCT06971614). MVR-T3011 is derived from herpes simplex virus.<br><br>During the induction treatment course, subjects will receive a low or high dose of MVR-T3011 once a week for 6 weeks, followed by a 6-week observation, and then a 3-month efficacy assessment. Subjects will then receive a second induction course, a maintenance therapy, or discontinue the study treatment based on the efficacy assessment results and as determined by their physician. |
| **NIH Guidelines Section** | **III-C-1** |

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| **Risk Assessment & Discussion** | • Herpes simplex virus (HSV) is a RG-2 agent.<br>• The novel vector MVR-T3011 contains attenuated HSV that is designed to preferentially replicate inside tumor cells.<br>• PPE consisting of gloves, rear-closing gown, surgical mask, shoe covers, head cover, and eye protection will be utilized when preparing or administering the agent.<br>• The pharmacy will prepare and handle the agent within Class II biological safety cabinet (BSC) under biosafety level 2 (BSL-2) containment.<br>• All materials that come into contact with the virus will be disposed of as biohazardous waste according to institutional and sponsor-provided procedures.<br>• Subjects, family members, and close contacts will be instructed on hygiene and infection control measures due to the live-attenuated herpes simplex virus nature of MVR-T3011. |
| **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.<br><br>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.<br><br>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 for preparation and administration of the agent. |
| **IBC Vote** | • A motion was made to provisionally approve this application pending the following conditions be met:<br>  • Modify the informed consent form to include: gangrene as a potential side effect of intratumoral injection, include meningitis and sepsis as potential side effects, and specify subject use of barrier method of contraception until six months after the final dose of MVR-T3011.<br>  • Use of Rush templates.<br>  • Correction of a typo on a recruitment poster.<br>  • Completion of required training by PI.<br>  • Specify that viral prep waste be decontaminated in bleach prior to disposal as biohazardous waste.<br><u>Votes</u>:<br>• 7-0-0-0<br>Conflicts of Interest: None |

| **New IBC Applications for Review** | |
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| **PI Name** | Miller, Rachel, Ph.D. |
| **ORA#** | 19050702-IBC01 |
| **Project Overview** | **III-D-4** This project uses a mouse model of osteoarthritis and will deliver adeno-associated virus vectors intraarticularly.<br>**III-F** x |
| **NIH Guidelines Section** | **III-D-4**<br>**III-F** |

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| **Risk Assessment & Discussion** | • Adeno-associated virus is a RG-1 agent.<br>• Agent will prepared and handled within Class II biological safety cabinet (BSC) under biosafety level 2 (BSL-2) containment.<br>• PPE consisting of lab coat, gloves, surgical mask, and eye protection will be utilized when preparing or administering the agent.<br>• Sharps that come into contact with the agent will be disposed of in a biohazardous sharps container.<br>• Non-sharps materials that come into contact with the agent will be disposed of as biohazardous waste. |
| **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.<br><br>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.<br><br>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-N for animal subjects.<br>• BSL-2 for preparation and administration of the agent. |
| **IBC Vote** | • A motion was made to provisionally approve this application pending the following conditions be met:<br>  • Completion of laboratory inspection.<br>  • Confirmation that transgene does not express a toxin and correction to corresponding application question.<br>  • Correction to agent risk group.<br>  • Resolution of discrepancies (personnel and number of animal subjects) between IBC and IACUC applications.<br>  • Clarification on role of each vector.<br>  • Naming of Dr. Miller as PI on Lab rules.<br>Votes:<br>• 6-0-0-0<br>Conflicts of Interest: None |

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| **New Business** | NIH initiative to modernize and strengthen biosafety oversight announced on 9/9/25.<br>• https://www.nih.gov/about-nih/nih-director/statements/nih-launches-initiative-modernize-strengthen-biosafety-oversight<br><br>Annual IBC registration will be submitted to NIH Office of Science Policy soon. |
| **Review of Incidents** | Nothing to report. |
| **Inspections/Ongoing Oversight** | Nothing to report. |
| **IBC Training** | Huntington's disease successfully treated for first time<br>• https://www.bbc.com/news/articles/cevz13xkxpro |
| **Public Comments** | There were no public comments. |

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| **Adjournment** | The IBC Chair moved to adjourn the meeting at 12:47 PM<br>The next meeting scheduled is for October 22, 2025 at 12:00 PM via Microsoft Teams. |