



**Institutional Biosafety Committee Meeting Minutes**

**Combined Meeting of  
National Institute of Health/Office of Science Technology File Nos. DE00003, FL 00051 and FL 00111**

**Meeting Date: March 12, 2026 (1Q Meeting)**

**Time: Noon**

**Locations: MS Teams**

PRESENT:

Eric Egelund, Pharm D., PhD  
Karl Mann, Process Coordinator  
Jasmine Jackson, Administrative Coordinator  
Mona Batish

Joseph Mazar, PhD  
Ed Mougey, PhD., Committee Chair  
Carrie Paquette-Straub  
Michael Primiani  
Amanda Hernan, PhD  
Kalmi Kniel, PhD

EXCUSED/ABSENT:

Rosa Rosario  
James Crutchfield, PhD.  
Ben Favret III, PhD

GUESTS:

COPIES:  
M. Carranza  
M. Davis, MD

The IBC Chair, Dr. Mougey, called the meeting to order at 12:02 PM

Discussion	Action/Outcome	Notes
<p><b>Roll Call and Conflict of Interest:</b> The IBC Chair, Dr. Mougey requested the IBC Coordinator to conduct rollcall.</p> <p>Dr. Mougey then welcomed our committee members and requested if any committee members had any conflicts of interest with any of the submittals or items on today’s agenda. No conflicts were declared. The new administrative liaison, Michael Primiani, was welcomed by all members.</p>	<p>Roll Call Recorded</p>	

<p><b>Approval of Minutes:</b>  Dr. Mougey requested a motion to approve our 4Q2025 meeting minutes. There were no requested changes and no additional discussion from committee members. Full committee approved the motion with no opposition.</p>	<p>Motion Approved</p>	<p>Motion made by A. Hernan and seconded by C. Paquette-Straub.</p>
<p><b>New/Renewal Applications:</b>  <u>Procedures Requiring Full Committee Review/Discussion:</u>  Dr. Evie Landry, IBC_2545 titled “A Phase 1/2, Open-Label, Multicenter Trial with a Single Ascending Dose Cohort with Unilateral Intracochlear Injection Followed by a Bilateral Injection Expansion Cohort to Evaluate the Safety, Tolerability, and Efficacy of DB-OTO in Children and Infants with Biallelic hOTOF Mutations.” Assigned reviewers Amanda Hernan and Eric Eglund provided their thoughts.</p>	<p>Approved with stipulations</p>	<p>Requested stipulations include an up-to-date CV with relevant qualifications listed, a study specific training plan, appropriate SOPs written and provided including a biosafety risk assessment.</p>
<p>Dr. Shunji Tomatsu - IBC_2552 titled “Gene delivery for Morquio A by AAV vectors.” Carrie Paquette-Straub and Mona Batish provided reviews for this submittal.</p>	<p>Approved with stipulations</p>	<p>Requested stipulations include complete AAV vector maps, gene sequences, updates to both section H and K, and expanded SOPs to include more study-specific information.</p>
<p>Dr. Abdul Hamid Omer - IBC_2547 titled “An Open-Label Study to Assess the Efficacy and Safety of Multiple Doses of Salanersen (BIIB115) Delivered Intrathecally to Treatment-Naïve, Presymptomatic Infants With Genetically Diagnosed Spinal Muscular Atrophy”. Joseph Mazar and Amanda Hernan provided reviews for this submittal</p>	<p>Approved with stipulations</p>	<p>Requested stipulations include detailed storage and transport instructions, clarification on preparation to usage time (4 hours limit), spill response, clarification on biospecimen collection and storage, and clearer indication of facility and rooms being utilized.</p>
<p><b>Expedited Procedures:</b>  None this quarter</p>		

<p><b>Tabled Procedures:</b>  Dr. Omer Abdul Hamid – IBC_2469 titled “A Phase 1/2/3 Open-label Study to Evaluate the Safety, Tolerability, Efficacy, Pharmacodynamics, and Pharmacokinetics of Intravenous RGX-202 Gene Therapy in Males with Duchenne Muscular Dystrophy (DMD) - RGX-202-110.” Original reviewers Joseph Mazar and Rosa Rosario, also reviewed by the Chair for final determination.</p>	<p>Approved with stipulations</p>	<p>Requested changes included specification of freezers, and exposure protocols including accidental needlesticks.</p>
<p><b>Waived Procedures:</b>  The Nemours Institutional Biosafety Process Coordinator makes determinations to waive submissions from IBC review, if appropriate. During 1Q2026, the Process Coordinator assessed, approved, and waived a total of 67 applications. The IBC Process Coordinator, K. Mann had advised the IBC Chair of no issues with any of waived proposed submittals. The IBC Chair advised that IBC waivers are included on the agenda to inform the Committee and notify our Research Administration Leaders. These studies are waived because they are covered by Joint Commission or other hospital review entities. The IBC Chair reminded committee members that if they wish to review or call for full committee review of any of these waived submissions, to please contact the IBC Coordinator.</p>		
<p><b>Disapproved Applications:</b> – None this quarter</p>		
<p><b>Open Discussion/Other:</b>  Facility Inspections completed in Wilmington  Decision Framework for External IBC Reliance vs. Nemours IBC as IBC of Record  REDCap update</p>		

With no further discussion, the IBC Chair motioned to adjourn the meeting and received seconds from many committee members.

Respectfully submitted by,

Ed  
Mougey

Digitally signed by  
Ed Mougey  
Date: 2026.06.16  
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Ed Mougey, Ph.D.  
IBC Chair