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 13, 2025 (1Q Meeting) **Time: 12:00 p.m.** **Locations: MS Teams**

PRESENT:

Eric Egelund, Pharm D., Ph.
Ben Favret III, Ph.D.
Nancy Little
Karl Mann, Process Coordinator
Jasmine Jackson, Administrative Coordinator
M. Davis, M.D.
Joseph Mazar, Ph.D.
Ed Mougey, Ph.D., Committee Chair
Carrie Paquette-Straub
Rosa Rosario
Mathew Rich
Jean Abate

EXCUSED/ABSENT:

Amanda Hernan, PhD
Kalmi Kniel, Ph.D.
Ronald Charlton
James Crutchfield, Ph.D.

GUESTS:

COPIES:
M. Carranza
M. Davis, M.D.

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

Discussion	Action/Outcome
Roll Call and Conflict of Interest: The IBC Chair, Dr. Mougey requested the IBC Coordinator to conduct rollcall. 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.	Roll Call Recorded
Approval of Minutes: Dr. Mougey requested a motion to approve our 4Q2024 meeting minutes. There were no requested changes and no additional discussion from committee members. Full committee approved with motion by Carrie Paquette-Straub, seconded by Mathew Rich	Motion Approved without changes
New/Renewal Applications: Procedures Requiring Full Committee Review/Discussion:	

Dr. Omer Abdul Hamid., IBC_1679 titled "A Phase 1/2, Randomized, Placebo-controlled, Double-blind, Study to Evaluate the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamic Effects of Single and Multiple Ascending Doses of AOC 1044 Administered Intravenously to Healthy Adult Volunteers and Participants with DMD Mutations Amenable to Exon 44 Skipping." Assigned reviewers Rosa Rosario and Uncas Benjamin Favrett III provided their thoughts.	This study was closed. No further IBC review is required.
Dr. Julian Zorrilla - IBC_1685 titled "ATLAS-OLE: An Open-label, Long-term Safety and Efficacy Study of Fitusiran in Patients with Hemophilia A or B, with or without Inhibitory Antibodies to Factor VIII or IX". M. Rich and E. Eglund provided reviews for this submittal. E. Eglund spoke of the possible clinical implications and expressed no concern for patient safety with regard to the study. M. Rich spoke of concerns for medication delivery in patient home settings. The request was made for a protocol for dealing with hazardous waste when not in the clinic.	Approved with stipulation that SOP must be provided for handling hazardous waste in home setting.
Dr. Shunji Tomatsu. - IBC_1741 titled Evaluate the novel REVec vector with human GALNS cDNA in MPS IVA mice". C. Paquette-Straub and K. Kneil provided reviews for this submittal. C. Paquette-Straub spoke of this submission being submitted as a clinical study in a clinical setting, which is incorrect. There were documents missing because of this incorrect selection. K. Mann pointed out that this study was previously denied because of an incorrect submission to the RedCap database.	Tabled with request of proper submission of section H and K for review.
Dr. Shunji Tomatsu. - IBC_1863 titled "Development of mRNA therapeutics for Morquio A syndrome". K. Mann and N. Little provided reviews for this submittal.	Previously reviewed and approved. Memo was sent on 2/13/25
Dr. David Blauvelt. - IBC_2116 titled "Comparison of hemocompatible coatings using a rabbit model". Dr. Langhans and K. Kniel provided reviews for this submittal. S. Langhans was not present but provided a review to the coordinator expressing no concerns. The submitted protocol was a change in study species, from rat to rabbit, and a complete SOP was provided for the handling of the study rabbits.	Approval with no stipulations.
Dr. Anilkumar Gopalakrishnapillai. - IBC_2145 titled "Development Of Down Syndrome Acute Myeloid Leukemia Models Using Combination of Induced Pluripotent Stem Cells and CRISPR/Cas9 Technologies: Understanding Leukemogenesis And A Roadmap To Novel Drug Discovery."	Approved with stipulation being the removal of Employee Health location from SOPs.

C. Paquette-Straub and N. Little provided reviews for this submittal. They expressed no concerns.	
Expedited Procedures: Dr. Elizabeth Wright-Jin – IBC_2061 titled "Metabolism and sex after neonatal hypoxic ischemic brain injury" Dr. David Blauvelt – IBC 2079 titled "Comparison of hemocompatible coatings using a rat model"	Expedited without concern.
Tabled Procedures: None this quarter	
Waived Procedures: The Nemours Institutional Biosafety Process Coordinator makes determinations to waive submissions from IBC review, if appropriate. During the 1Q2025, the Process Coordinator assessed, approved, and waived a total of 75 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.	
Disapproved Applications: – None this quarter	
Open Discussion/Other: Ticket for RedCap review submitted to brand department for approval Ticket submitted for the creation of an internal IBC site for associate reference Clarification on what protocols must be submitted for IBC approval	

With no further discussion, the IBC Chair motioned to adjourn the meeting at 12:50pm and received seconds from many committee members.

Respectfully submitted by,

Ed Mougey

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Date: 2025.06.12 13:49:35 -04'00'

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Ed Mougey, Ph.D.
IBC Chair