



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: June 12, 2025 (2Q Meeting)

Time: 12:00 p.m.

Locations: MS Teams

PRESENT:

Eric Egelund, Pharm D., Ph.

Karl Mann, Process Coordinator

Jasmine Jackson, Administrative Coordinator

Amanda Hernan, PhD

Kalmi Kniel, Ph.D.

Ed Mougey, Ph.D., Committee Chair

Carrie Paquette-Straub

Mathew Rich

Jean Abate

EXCUSED:

Nancy Little

Rosa Rosario

GUESTS:

COPIES:

M. Carranza

M. Davis, M.D.

ABSENT:

Ben Favret III, Ph.D.

Joseph Mazar, Ph.D.

Ronald Charlton

James Crutchfield, Ph.D

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

| Discussion | Action/Outcome |
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| 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: | Motion Approved without changes |

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| Dr. Mougey requested a motion to approve our 1Q2025 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 | |
| New/Renewal Applications: Chair asked for any conflict of interest, none were disclosed. <u>Procedures Requiring Full Committee Review/Discussion:</u> Dr. Shunji Tomatsu, IBC_2214 titled “RNA virus-based episomal vector gene therapy.” Assigned reviewers Carrie Paquette-Straub and Nancy Little provided their thoughts. | C. Paquette-Straub discussed the several missing documents and incorrect classification on this application. Since it is an update to application 1741, which is now complete, this application will be disregarded. |
| Dr. Xuyi (Kevin) Yue - IBC_2231 titled “PET Imaging Brain Lymphatic System by Targeting VEGFR3”. Dr. Amanda Hernan and Dr. Kalmia Kniel provided reviews for this submittal. | Dr. Hernan provided an in-depth review of several missing parts of this application including: lack of description of training practices and assessment, the inability to lock doors as stated in submitted SOP, listing latex gloves when nitrile are recommended, no clear path for transporting animals or provided SOP for animal transport, no procedure for storage and disposal of infected tissues, no F18 storage procedures listed, and no storage for tools used on infected tissue listed. Committee agreed to approve with the stipulation that all of the above issues be addressed before final approval. |
| Expedited Procedures: None this quarter | |
| Tabled Procedures: Dr. Shunji Tomatsu. - IBC_1741 titled Evaluate the novel REVec vector with human GALNS cDNA in MPS IVA mice”. | C. Paquette-Straub asked that any chemicals listed in the section K form that are not being used in the proposed experiment be removed. Also requested that all other chemicals being handled be added to the section H Committee agreed to approve with these stipulations. |
| Conditionally Approved Procedures: 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”. | No response has been received. Will follow up again and table until requested SOP is provided by investigator. |
| Waived Procedures: | |

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| <p>The Nemours Institutional Biosafety Process Coordinator makes determinations to waive submissions from IBC review, if appropriate. During the 2Q2025, the Process Coordinator assessed, approved, and waived a total of <u>101 applications</u>. 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>K. Mann addressed the increase in waived procedures as a result of more retrospective and review studies being submitted correctly for IBC review. Dr. Mougey agreed that this was a positive development, and all investigators should be encouraged to submitted all research for review.</p> |
| <p>Disapproved Applications: – None this quarter</p> | |
| <p>Open Discussion/Other: Migration to the new IBC REDCap IBC REDcap training sessions request</p> | <p>A protocol is being developed for a non-response from investigators. This will address how long a procedure can be tabled until it will be administratively closed. When migration to new REDCap is complete the old platform will be maintained for three years or until all studies on the platform have expired.</p> <p>Dr. Mougey addressed the compliance department’s push for more uniform audit readiness. Committee will continue to work with compliance to make sure that all locations are prepared for any possible outside audit.</p> |

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, Ph.D.
IBC Chair