



Brown University Health - Institutional Biosafety Committee

Minutes

July 7, 2025 Videoconference

Present: Dr. Jayasuriya, (Chairperson), Dr. Dubielecka-Szczerba (Vice Chairperson), Dr. Gregory, Ms. Hemendinger, Dr. Li (Assoc. Chair), Mr. McEvoy and Mr. O'Reilly

Absent: Dr. Jackson, Dr. Mehta, and Dr. Merley

Investigators Submitting Applications for Review: Dr. Lefort

Support Staff: Ms. Poore

Note: Unless otherwise stated all motions were unanimously approved for 3 years.

After determining that quorum was met, Dr. Jayasuriya convened the meeting at 12:03 p.m.

The following voting members were present when the meeting began: Dr. Jayasuriya, Dr.

Dubielecka-Szczerba, Dr. Gregory, Dr. Li, Mr. McEvoy, and Mr. O'Reilly

Welcome and Opening Remarks: The IBC chair read the COI statement aloud to remind members it is their responsibility to identify if they have a conflict of interest and to recuse themselves from review of that item.

ITEMS

1 Review of Previous Minutes

1.1 Minutes from 5/5/25

Committee Action: The minutes were approved as submitted.

Vote: Number of members present 6, Approved 6, Opposed 0, Abstained 0, Recused 0

2 Start of Hazard Business

NOTE: Dr. Dubielecka assumed responsibilities of the Chair for this portion of the meeting.

Ms. Hemendinger arrived after the vote was taken for the minutes.

3 New Studies Hazard

3.1 [2335439-1] Cytarabine

PI: Craig Lefort, PhD

Reference Number: 5023-25

Sponsor: NIH/NIGMS
Submission Type: New Project

Review Type: Full Committee Review
Primary Reviewer: Patrycja Dubielecka-Szczerba

Discussion:

- Dr. Lefort provided an overview of the project. Cytarabine and Doxorubicin are chemotherapy agents used in human cancer patients. These agents disrupt DNA synthesis in rapidly dividing cells. As a result, these patients become neutropenic. These two agents will be used in a mouse model of neutropenia in order to evaluate the efficacy of cellular treatments under development.
- An application for the use of Doxorubicin has been processed for expedited review, see item 4.1 below.
- Dr. Lefort verified that the dose and treatment regimen is based upon published studies.
- Training with the Chair regarding the use of these materials is scheduled for later in the month.

Committee Action: The committee voted to approve the proposal as submitted, pending completion of agent specific training.

Vote: Number of members present 7 Approved 7 Opposed 0 Abstained 0 Recused 0

4 Expedited and Revision Reviews Hazard

4.1 [2335456-1] Doxorubicin

PI: Craig Lefort, PhD
Reference Number: 5024-25
Sponsor: NIH/NIGMS
Submission Type: New Project

Review Type: Expedited Review

4.2 **[2319029-2] Metformin**

PI: Sendurai Mani
Reference Number: 501625
Submission Type: Response/Follow-Up

Review Type: Expedited Review
Action: Approved
Effective Date: May 15, 2025
Project Status: Active
Project Expiration: May 14, 2028
Remarks: corrections from pkg 1

4.3 **[2316538-2] Volasertib**

PI: Sendurai Mani
Reference Number: 501225
Sponsor: NIH NCI
Submission Type: Response/Follow-Up

Review Type: Expedited Review
Action: Approved
Effective Date: May 15, 2025
Project Status: Active
Project Expiration: May 14, 2028
Remarks: corrections from pkg 1

4.4 **[2332618-1] Tamoxifen**

PI: Ruhul Abid, MD, PhD
Reference Number: 502025
Submission Type: New Project

Review Type: Expedited Review

4.5 **[2333237-1] Use of tamoxifen for inducing cre**

recombinase PI: Shougang Zhuang
Reference Number: 502225
Sponsor: NIH grant
Submission Type: New Project

Review Type: Expedited Review

5.1 [1637391-8] Streptozocin (STZ) and Ruboxistaurin

PI: Jun Feng, M.D. PhD
Reference Number: BLS 503520
Sponsor: NIH
Submission Type: Closure/Final Report

Review Type: Administrative Review
Action: Terminated
Effective Date: May 29, 2025
Project Status: Terminated

5.2 [2221746-4] COVID-19 and Endothelial Function

PI: Jun Feng, MD, PhD
Sponsor: Intramural funds
Submission Type: Closure/Final Report

Review Type: Administrative Review
Action: Terminated
Effective Date: May 27, 2025
Project Status: Terminated

6 Other Business Hazard

Dr. Dubielecka explained that applications for the use of Doxorubicin are currently processed for Expedited Review using a standardized application form. She noted that Cytarabine is similar with regards to handling and containment, and is actually less hazardous than doxorubicin. Accordingly, Dr. Dubielecka asked the members to consider adding Cytarabine to the list of agents eligible for Expedited IBC review. Ms. Poore will prepare a draft expedited application form for committee consideration at the next meeting.

7 New Studies DNA

8 Continuing Reviews DNA

9 Revisions- Full Board DNA

10 Administrative Check-In

10.1 [640460-20] Role of Abi1 in retention of quiescent drug-resistant leukemic stem cells in the bone marrow niche

PI: Patrycja Dubielecka, PhD
Reference Number: 008513, lentivirus, retrovirus
Sponsor: Department funds
Submission Type: Continuing Review/Progress Report

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|----------------------------|------------------|
| Review Type: | Expedited Review |
| Action: | Acknowledged |
| Effective Date: | May 23, 2025 |
| Project Status: | Active |
| Project Expiration: | August 6, 2026 |

11 Expedited and Revision Reviews DNA

11.1 [2261837-2] IBC Committee: LS-P-IGNYTE-3: A Randomized, Controlled, Multicenter, Phase 3 Clinical Study Comparing Vusolimogene Oderparepvec in Combination with Nivolumab Versus Treatment of Physician' s Choice in Patients with Advanced Melanoma That Has Progressed on an Anti-PD-1 and an Anti-CTLA-4 Containing Treatment Regimen [IGNYTE-3]

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|--------------------------|------------------------|
| PI: | Maria Constantinou, MD |
| Reference Number: | 501325 ceded to WCG |
| Sponsor: | Replimune, Inc. |
| Submission Type: | Response/Follow-Up |

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|----------------------------|------------------------|
| Review Type: | Administrative Review |
| Action: | Acknowledged |
| Effective Date: | May 14, 2025 |
| Project Status: | Active |
| Project Expiration: | March 31, 2026 |
| Next Report Due: | April 1, 2026 |
| Remarks: | corrections from pkg 1 |

11.2 [1480956-64] COBREII Lentivirus Construct Core

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|--------------------------|--------------------------------|
| PI: | Olin Liang, Ph.D. |
| Reference Number: | 504619, lentivirus, retrovirus |
| Sponsor: | Federal |
| Submission Type: | Amendment/Modification |

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|----------------------------|------------------|
| Review Type: | Expedited Review |
| Action: | Approved |
| Effective Date: | May 29, 2025 |
| Project Status: | Active |
| Project Expiration: | July 31, 2026 |
| Next Report Due: | June 16, 2025 |
| Remarks: | add personnel |

11.3 [1991530-7] Transcriptomal heterogeneity, epigenetic variation and cytokine regulation within chordoma

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|--------------------------|-----------------------------|
| PI: | Margot Martinez-Moreno, PhD |
| Reference Number: | 500223 lentivirus |

Sponsor: Departmental funds
Submission Type: Amendment/Modification
Review Type: Expedited Review

Action: Approved
Effective Date: June 26, 2025
Project Status: Active
Project Expiration: December 3, 2026
Next Report Due: November 15, 2025
Remarks: Add Aldrich 4th floor labs and personnel.

11.4 **[1991530-8] Neurosurgery Core Laboratories Research**

PI: Margot Martinez-Moreno, PhD
Reference Number: 500223 lentivirus
Sponsor: Departmental funds
Submission Type: Amendment/Modification

Review Type: Administrative Review
Action: Acknowledged
Effective Date: June 26, 2025
Project Status: Active
Project Expiration: December 3, 2026
Next Report Due: November 15, 2025
Remarks: administrative- revise title

12 **Administrative Reviews DNA**

12.1 **[640106-18] Regulation of cardiac fibroblasts function by miRNAs**

PI: Ulrike Mende, MD
Reference Number: 008213, adeno-associated vectors, adenovirus
Submission Type: Continuing Review/Progress Report

Review Type: Administrative Review
Action: Acknowledged
Effective Date: June 19, 2025
Project Status: Active
Project Expiration: August 13, 2026

13 **Exempt DNA**

14 **Other Business DNA**

14.1 **Self-Assessment, sections 73-79**

Discussion:

- No deficiencies were identified under this portion of the self-assessment.

15 End of DNA Business

The meeting adjourned at 12:16 p.m.