

Brown University Health - Institutional Biosafety Committee Minutes

September 8, 2025 Videoconference

Present: Dr. Jayasuriya, (Chairperson), Dr. Gregory, DR. Jackson, Dr. Li (Assoc. Chair), Mr.

McEvoy, and Dr. Merley

Absent: Dr. Dubielecka-Szczerba (Vice Chairperson), Ms. Hemendinger, Dr. Mehta, and Mr.

O'Reilly

Investigators Submitting Applications for Review: Dr. Abid (presented by Dr. Brinck)

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 12:01 p.m. The following voting members were present when the meeting began: Dr. Jayasuriya, (Chairperson), Dr. Gregory, D1. Jackson, Dr. Li (Assoc. Chair), Mr. McEvoy, and Dr. Merley

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.

1 Review of Previous Minutes

1.1 **Minutes from 7/7/25**

Committee Action: The minutes were approved as submitted.

<u>Vote</u>: Number of members present <u>6</u>, Approved <u>6</u>, Opposed <u>0</u>, Abstained <u>0</u>, Recused <u>0</u>

2 Start of Hazard Business

3 New Studies Hazard

3.1 [1501635-6] Monocrotaline

PI: Ruhul Abid, MD, PhD

Reference Number: BLS 506419

Sponsor: NIH

Submission Type: Continuing Review/Progress Report

Review Type: Full Committee Review

Primary Reviewer: Patrycia Dubielecka-Szczerba

Discussion:

- This is a third year renewal for the use of monocrotaline in animals.
- Dr. Brinck Texeira provided a brief overview of the project, noting that there are currently no plans to use this agent in animals. The researchers are requesting permission to keep approval open in case additional experiments are requested as part of a grant submission or publication.
- There were no questions.

<u>Committee Action</u>: The committee voted to approve the proposal as submitted.

<u>Vote</u>: Number of members present _6_ Approved _6_ Opposed <u>0</u> Abstained _0_Recused _0_

4 Expedited and Revision Reviews Hazard

4.1 [2353977-1] Multimorbidity Subphenotypes and Extracellular Vesicles in Critically-III Patients with Sepsis-ARDS

PI: Maya Cohen, MD

Reference Number: 502825

Submission Type: New Project Review Type: Expedited Review

Action: Approved

Effective Date: August 13, 2025

Project Status: Active

Project Expiration: August 12, 2028

4.2 [2357352-1] Tamoxifen / 4-Hydroxytamoxifen

PI: Craig Lefort, PhD

Reference Number: 502925 **Submission Type:** New Project

Review Type: Expedited Review

5 Administrative Reviews Hazard

6 Other Business Hazard

6.1 Draft forms for expedited review of Cytarabine

<u>Discussion</u>: Cytarabine is a common chemotherapy agent. Handling is consistent with other similar agents. The members agreed that going forward, expedited review for the use of this agent is appropriate.

<u>Committee Action</u>: The committee voted to approve the forms as submitted.

<u>Vote</u>: Number of members present _6_ Approved _6_ Opposed <u>0</u> Abstained _0_Recused _0_

6.2 Draft form- manipulation of human samples known to be infectious

<u>Discussion</u>: A researcher recently reached out to the IBC Chairs regarding the use of clinical samples from patients diagnosed with sepsis. While all personnel are trained to handle patient samples under standard precautions, the chairs determined that manipulating patient samples known to be infectious requires additional attention. Accordingly, a new form was developed based upon the COVID sample form and the Expedited form for the use of human source samples in animals.

Committee Action: The committee voted to approve the form as submitted.

Vote: Number of members present _6_ Approved _6_ Opposed 0 Abstained _0_Recused _0_

7 New Studies DNA

8 Continuing Reviews DNA

9 Revisions- Full Board DNA

10 Administrative Check-In

10.1 **[1952518-2] Doxorubicin**

PI: richard terek, MD

Reference Number: BLS 503922

Submission Type: Continuing Review/Progress Report

Review Type: Expedited Review

Action: Approved

Effective Date: July 17, 2025

Project Status: Active

Project Expiration: July 16, 2028

10.2 [1480956-66] COBREII Lentivirus Construct Core

PI: Olin Liang, Ph.D.

Reference Number: 504619, lentivirus, retrovirus

Sponsor: Federal

Submission Type: Continuing Review/Progress Report

Review Type: Administrative Review

Action: Acknowledged Effective Date: July 8, 2025

Project Status: Active

Project Expiration: July 31, 2026

10.3 **[633019-24]** Use of rAAV2-bFGF and rAAV2-VEGF to Improve Wound Healing in vitro and in

vivo

PI: Paul Liu, MD

Reference Number: 018611, adeno-associated virus

Submission Type: Continuing Review/Progress Report

Review Type: Administrative Review

Action: Acknowledged Effective Date: July 8, 2025

Project Status: Active

Project Expiration: September 10, 2026

10.4 [2210828-3] A splicing-generated protein of hepatitis B virus in chronic viral infection

PI: Shuping Tong

Reference Number: 502524 **Sponsor:** NIH/NIAID

Submission Type: Continuing Review/Progress Report

Review Type: Administrative Review

Action: Acknowledged Effective Date: August 5, 2025

Project Status: Active

Project Expiration: September 8, 2027

Next Report Due: September 1, 2026

10.5 [2237805-4] IBC Committee: LS-P-MuSIC (BO45230): A Randomized Phase II, Double-Blind, Multicenter Study Evaluating The Efficacy And Safety Of Autogene Cevumeran Plus Nivolumab Versus Nivolumab As Adjuvant Therapy In Patients With High-Risk Muscle-Invasive Urothelial Carcinoma

PI: Galina Lagos, MD

Reference Number: 503024

Sponsor: F. Hoffmann-La Roche Ltd

Submission Type: Continuing Review/Progress Report

Review Type: Administrative Review

Action: Acknowledged
Effective Date: August 7, 2025

Project Status: Active

Project Expiration: October 6, 2027

Next Report Due: October 1, 2026

11 Expedited and Revision Reviews DNA

11.1 [1480956-65] COBREII Lentivirus Construct Core

PI: Olin Liang, Ph.D.

Reference Number: 504619, lentivirus, retrovirus

Sponsor: Federal

Submission Type: Amendment/Modification

Review Type: Expedited Review

Action: Approved Effective Date: July 22, 2025

Project Status: Active

Project Expiration: July 31, 2026

Remarks: add personnel

11.2 [1991530-9] Neurosurgery Core Laboratories Research

PI: Margot Martinez-Moreno, PhD

Reference Number: 500223 lentivirus

Sponsor: Departmental funds

Submission Type: Amendment/Modification

Review Type: Expedited Review

Action: Approved Effective Date: July 22, 2025

Project Status: Active

Project Expiration: December 3, 2026

Next Report Due: November 15, 2025

Remarks: insert a Luciferase non-replicant vector into human cells for use in

animals, add agents from Dr. Tapinos to BL-2 inventory, transfect plasmids for GFP expression, transfect human cells with siRNA

11.3 [2264458-4] A Phase 3, Randomized Study of Adjuvant Cretostimogene Grenadenorepvec versus Observation for the Treatment of Intermediate Risk Non-Muscle Invasive Bladder Cancer (IR-NMIBC) Following Transurethral Resection of Bladder Tumor (TURBT)

PI: Dragan Golijanin, MD

Reference Number: 503724

Sponsor: CG Oncology, Inc.

Submission Type: Amendment/Modification

Review Type: Expedited Review

Remarks: protocol changes not relating to the recombinant agent

- 12 Administrative Reviews DNA
- 13 Exempt DNA
- 14 Other Business DNA
- 15 End of DNA Business

The meeting adjourned at 12:16 p.m.