Brown University Health - Institutional Biosafety Committee Minutes

April 6, 2026 Videoconference

Present: Dr. Jayasuriya, (Chairperson), Dr. Dubielecka-Szczerba (Vice Chairperson), Ms. Brilliant, Mr. Carrera (alternate for Mr. McEvoy), Mr. Dooner, Dr. Helwig, Dr. Li (Associate Chair), Mr. McEvoy, and Mr. O'Reilly

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

Investigators Submitting Applications for Review: Dr. Nau and Dr. Mani

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 12:04 p.m.
The following voting members were present when the meeting began: Dr. Jayasuriya, Dr. Dubielecka-Szczerba, Ms. Brilliant, Mr. Dooner, Dr. Helwig, Dr. Li, Mr. McEvoy, and Mr. O'Reilly

Mr. Carrera, alternate for Mr. McEvoy, was present but did not participate in the vote for any item discussed at this meeting.

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 3/2/26**
Committee Action: The minutes were approved as submitted.

Vote: Number of members present 8, Approved 7, Opposed 0, Abstained 1 Recused 0

1.2 **Minutes from 3/12/26 meeting**
Committee Action: The minutes were approved as submitted.

Vote: Number of members present 8, Approved 7, Opposed 0, Abstained 1 Recused 0

2 **Start of DNA business**

3 **New Studies DNA**

4 **Continuing Reviews DNA**

4.1 **[759582-30] Microbial Pathogenesis and Drug Discovery PI:** Gerard Nau, MD, PhD **Reference Number:** 0117-15 adenovirus, lentivirus

Submission Type: Continuing Review/Progress Report
Review Type: Full Committee Review Primary Reviewer: Jisu Li, Chathuraka Jayasuriya

Presented by Dr. Nau

Discussion: This progress report is submitted for third-year renewal.

Dr. Nau provided a brief overview of the project, noting that the work focuses on finding new treatments for infectious disease. The team is currently working with antimicrobial compounds.

A member noted that question 5b relating to viral vectors has to responses. Dr. Nau clarified that the "no" response reflects legacy stocks of adenovirus which are maintained in the inventory but no longer in use and the "N/A" response references pseudotyped lentivirus.

The members requested clarification regarding the description of BL-2 agents in table 3a, as some of the details are more extensive than requested on the form and were not necessarily placed under an appropriate column heading.

Members requested clarification regarding the new constructs referenced under question 7. Dr. Nau explained that this refers to plans for a new plasmid reporter construct detailed under question 3c

Requested corrections:

- Please upload copies of the Lab Safety Inspection Certificate and the Recombinant DNA BSL-2 Safety Inspection Certificate
- Progress Report form, Item 3a table of vectors refers to plasmids that will be used to construct viral vectors. Please keep it simple and add individual vectors per row. It is not necessary to put every plasmid that is used to produce a viral vector into a single row.
    - Rows 2, 3, and 4 of the table are listed as "plan to construct, purchase, or obtain". These agents could be deleted if there are no current plans to obtain the agents
    - Column 2 ("Supplier name"): For "Nau Lab," the four vector names should be moved to Column 1 under "Vector or agent name."
    - To reduce redundancy in Column 3 ("Expressed gene"), list the reporter genes (luciferase and GFP) and pseudotyping genes only once, and provide additional details in section 3a. For example: pseudotyped virus will be generated by co-transfection of four plasmid backbones together with the corresponding pseudotyping genes listed.
- Item 5b, it would be helpful to include a brief statement to which agents are not replication competent and which are "N/A"
- Item 7 states that additional vectors have been added but reported testing dates are outside the 3-year time frame. Please clarify and/or provide updated testing results for strains added.
- Please review the lentiviral Safety Sheet originally submitted with IRBNet pkg 7 and update to reflect current agents in use, as applicable

The IBC reviewed this project with regard to: potential virulence, pathogenicity or environmental stability of the agent; the types of manipulations planned; the source and nature of the inserted DNA sequences; and the host and vectors to be used. IBC assessment is as follows:

Recombinant DNA materials will be used in humans	Yes	X No
Recombinant DNA materials will be used in animals.	Yes	X No
Training and Expertise of personnel is adequate.	X Yes	No
Facilities, procedures and practices are adequate.	X Yes	No
Annual testing for replication competence is necessary.	X Yes	X No

Biohazard containment level _____ BL2 _____

Applicable Section of the NIH Guidelines: _____III-D _____

Committee Action: The committee voted to require modifications to secure approval. Dr. Jayasuriya and Dr. Li will serve as designated reviewers for the requested corrections.

Vote: Number of members present 8, Approved 8 Opposed 0 Abstained 0, Recused 0

4.2 **[2016881-10] The role of FOXC2 and vimentin in EMT and cancer stem cells PI:**

Sendurai Mani

Reference Number: 501023 lentivirus, retrovirus

Submission Type: Continuing Review/Progress Report

Review Type: Full Committee Review
Presented by N. Kuburich and K. Attri

Discussion: This progress report is submitted for third-year renewal.

Dr. Kuburich provided a brief summary of this project, noting that lentivirus systems are used to transduce and insert genes into cancer cells and then the researchers work to characterize the phenotype.

Requested corrections:

- Please upload copies of the Lab Safety Inspection Certificate and the Recombinant DNA BSL-2 Safety Inspection Certificate
- Progress report form, item 7, please include a brief description of the genes that are being added/modified in the study.
- Item 5 states that vectors have been added since the last renewal date yet the last testing date listed is 5/28/2024 (nearly 2 years ago). Please clarify and/or provide updated testing results for strains added.

The IBC reviewed this project with regard to: potential virulence, pathogenicity or environmental stability of the agent; the types of manipulations planned; the source and nature of the inserted DNA sequences; and the host and vectors to be used. IBC assessment is as follows:

Recombinant DNA materials will be used in humans	Yes	X No
Recombinant DNA materials will be used in animals.	X Yes	No
Training and Expertise of personnel is adequate.	X Yes	No
Facilities, procedures and practices are adequate.	X Yes	No
Annual testing for replication competence is necessary.	X Yes	X No

Biohazard containment level _____ BL2 _____
Applicable Section of the NIH Guidelines: _____III-D _____

Committee Action: The committee voted to require modifications to secure approval. Dr. Jayasuriya will serve as the designated reviewer for the requested corrections.

Vote: Number of members present 8, Approved 8 Opposed 0 Abstained 0, Recused 0

5 **Revisions- Full Board DNA**

6 **Administrative Check-In**

7 **Expedited and Revision Reviews DNA**

7.1 **[1480956-68] COBREII Lentivirus Construct Core PI:** Olin Liang, Ph.D.

Reference Number: 504619, lentivirus, retrovirus
Sponsor: Federal
Submission Type: Response/Follow-Up

Review Type: Expedited Review
Action: Approved
Effective Date: February 27, 2026
Project Status: Active
Project Expiration: July 31, 2026
Remarks: requested corrections from pkg 67

7.2 **[2028162-10] Conditionally Replicative Oncolytic Adenovirus PI:** Olin Liang, Ph.D.

Reference Number: 502223 adenovirus **Sponsor:** Brown Physicians Inc.

Submission Type: Response/Follow-Up

Review Type: Expedited Review

Action: Approved

Effective Date: March 2, 2026

Project Status: Active

Project Expiration: March 1, 2029

Next Report Due: March 1, 2027

Remarks: corrections from pkg 8

7.3 **[2416621-2] Viral Particle Generation for Functional Gene Knockdown Studies in Meniscal Cells**

PI: Chathuraka Jayasuriya, PhD

Reference Number: 500126 lentivirus **Sponsor:** Orthopedics **Submission Type:** Response/Follow-Up

Review Type: Expedited Review

7.4 **[2237805-8] 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: Revision

Review Type: Administrative Review

Action: Acknowledged

Effective Date: March 24, 2026

Project Status: Active

Project Expiration: October 6, 2027

Next Report Due: October 1, 2026

Remarks: closed to enrollment

8 **Administrative Reviews DNA**

9 **Exempt DNA**

10 **Other Business DNA**

11 **End of DNA Business**

NOTE: Dr. Dubielecka-Szczerba assumed responsibilities as Chair for the remainder of the meeting.

12 **Start of Hazard Business**

13 **New Studies Hazard**

13.1 **[2028806-3] Withaferin-A**

PI:	Sendurai Mani, Ph.D.
Reference Number:	BLS 501823
Sponsor:	National Cancer Institute
Submission Type:	Continuing Review/Progress Report
Review Type:	Full Committee Review Primary Reviewer:
	Patrycia Dubielecka-Szczerba **Remarks:**
	Third year renewal

Discussion: This application has been submitted for third-year renewal.

Dr. Kuburich explained that Withaferin-A has been shown to have anti-cancer effects in previous studies.

Requested corrections: None

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

Vote: Number of members present 8, Approved 8 Opposed 0 Abstained 0, Recused 0

13.2 **[2029123-3] Carboplatin**

PI:	Sendurai Mani
Reference Number:	502023
Submission Type:	Continuing Review/Progress Report
Review Type:	Full Committee Review Primary Reviewer:
	Patrycia Dubielecka-Szczerba **Remarks:**
	Third year renewal

Discussion: This application has been submitted for third-year renewal.

Dr. Kuburich explained that Carboplatin is a chemotherapy agent which is being used to evaluate treatment effects on cancer cells.

Requested corrections: None

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

Vote: Number of members present 8, Approved 8 Opposed 0 Abstained 0, Recused 0

13.3 **[2041292-3] Doxycycline**

PI: Sendurai Mani, Ph.D.

Reference Number: BLS 502523

Submission Type: Continuing Review/Progress Report

Review Type: Full Committee Review Primary Reviewer:

Patrycia Dubielecka-Szczerba **Remarks:**
Third year renewal

Discussion: This application has been submitted for third-year renewal.

Dr. Kuburich explained that Doxycycline is an antibiotic which is used induce expression of genes of interest in certain strains of transgenic animals.

Dr. Kuburich verified that Doxycycline chow will be purchased from a commercial vendor.

Requested corrections: None

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

Vote: Number of members present 8, Approved 8 Opposed 0 Abstained 0, Recused 0

NOTE: Items 13.4, 13.5, and 13.6 submitted by Dr. Mani will be reviewed next month. Due to an administrative error, they were not shared with the members prior to the meeting.

13.4 **[2424736-1] OXALIPLATIN**

PI: Sendurai Mani

Reference Number: 500326

13.5 **[2424742-1] FOLINIC ACID**

PI: Sendurai Mani

Reference Number: 500426

13.6 **[2424744-1] IRINOTECAN**

PI: Sendurai Mani

Reference Number: 500526

14 **Expedited and Revision Reviews Hazard**

14.1 **[2022890-2] DOXORUBICIN**

PI: Sendurai Mani

Reference Number: BLS 501323

Review Type: Expedited Review

Action: Approved

Effective Date: March 26, 2026

Project Status: Active

Project Expiration: March 25, 2029

Remarks: Third year renewal

14.2 **[2023532-2] Human cell lines in mice PI:**

	Sendurai Mani
Reference Number:	BLS 501223
Submission Type:	Continuing Review/Progress Report
Review Type:	Expedited Review
Action:	Approved
Effective Date:	March 26, 2026
Project Status:	Active
Project Expiration:	March 25, 2029
Remarks:	Third year renewal

14.3 **[2047664-3] Human cells in immunodeficient animals PI:**

	Patricia Sullivan, MD
Reference Number:	BLS 502823
Submission Type:	Continuing Review/Progress Report
Review Type:	Expedited Review
Remarks:	third year renewal

15 **Administrative Reviews Hazard**

16 **Other Business Hazard**

16.1 **For discussion- revised documents relating to containment of animals implanted with human source cells, including genetically modified human source cells.**

The expedited application form for the use of human source cells in animals has been updated to require IBC review for the use of human source cells in any animal, not just immunodeficient mice. Animal facility contact information and expanded containment descriptions were also added.

Discussion: Members noted that extracellular vesicles (EVs) may carry potentially infectious agents (e.g. virus) and thus may present a risk to animal care staff. The members agreed to add a statement to include animals treated with extracellular vesicles (EVs).

Committee Action: The committee voted to approve the updated documents as amended.

Vote: Number of members present 8, Approved 8 Opposed 0 Abstained 0, Recused 0

16.2 **For discussion- allow expedited review for the use of Doxycycline HCL. Draft Expedited application form and safety checklist submitted for review**

Committee Action: The committee voted to place Doxycycline on the list of agents eligible for expedited review.

Vote: Number of members present 8, Approved 8 Opposed 0 Abstained 0, Recused 0

16.3 **For discussion: Updated Recombinant DNA Application form**

The DNA application form was updated to include administrative changes and one new question regarding containment for animals treated with genetically modified cells.

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

Vote: Number of members present 8, Approved 8 Opposed 0 Abstained 0, Recused 0

16.4 **For discussion- draft Biosafety Manual for BSL-2 labs**

NIH requires that BLS-2 labs maintain a Biosafety Manual. Members of the committee volunteered to review the first draft and report back to the committee next month.

The meeting adjourned at 1:09 p.m.