Brown University Health - Institutional Biosafety Committee Minutes

December 1, 2025 Videoconference

Present: Dr. Jayasuriya, (Chairperson), Dr. Dubielecka-Szczerba (Vice Chairperson), Ms. Brilliant, Mr. Carrera, Dr. Gregory, Dr. Helwig, Dr. Li, and Mr. McEvoy

Absent: Ms. Hemendinger, Dr. Jackson, Dr. Mehta, and Mr. O'Reilly

Investigators Submitting Applications for Review: Dr. Mallik, Dr. Oldham, and Dr. Liang

Guests: Dr. Teboul, Dr. Oldham, and Dr. Liang

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, Dr. Gregory, Dr. Helwig, and Mr. McEvoy

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 from October 6, 2025**
Committee Action: The minutes were approved as submitted.

Vote: Number of members present 6, Approved 4, Opposed 0, Abstained 2, Recused 0

2 **New Studies DNA**

2.1 **[2383757-1] [IBC] Neural circuits underlying disorders of consciousness**

PI:	Athar Malik, MD, PhD
Reference Number:	504025
Submission Type:	New Project
Review Type:	Full Committee Review
Primary Reviewer:	Cynthia Jackson, Chathuraka Jayasuriya

Discussion:

- Dr. Teboul provided a brief overview of the project. The team will use AAV to facilitate expression of experimental transgenes in the mouse nervous system.
- Dr. Teboul verified that the team will not be making viral particles in the lab.
- Members asked how replication incompetence is assured. Dr. Teboul stated that this assurance is provided by the commercial supplier.
- The members agreed that AAV will be handled under BL-1 containment. Because the agents will be administered to animals, the lab space should still be inspected by the IBC.
- Members requested clarification regarding the reference in the abstract regarding helper-dependent systems, noting that the use of helper viruses would elevate the project to BL-2

handling and containment. Dr. Teboul stated that there are no current plans for the use of helper viruses.

- Members noted that if helper viruses (i.e. adenovirus, retrovirus) were involved in the production of the rAAV at any point by the manufacturer, it's important to make sure that these viruses are not present (or contaminate) the rAAV product. This is especially important because the lab is proposing to use BSL1 handling and not BSL2. Please provide official documentation from Addgene for why each vector can be handled under BSL1 and not BSL2.

Requested Corrections to application forms:

- It seems that all viral vectors will be purchased. Please verify that virus particles will be manufactured in-house for this project.
- Abstract, revise the reference to helper-dependent systems
- rAAV protocol: A significant level of detail regarding procedures is missing. Please include a comprehensive description of how you will be administering the AAV to animals. Which vectors will you use (including transgene) and will each vector be administered in the same way? (i.e. tail vain, IP, interorbital).
- Pg. 1, typo, "Viruses will be injected IP, tail vein IP, RO, or intracranially depending on the specific experiment." - The 2nd IP should be IV; and RO = retroorbital (should be defined at first use)
- Under Viral Administration, describe the procedure for all methods of rAAV administration, as only the method for intracranial injection is described
- Rec DNA application form, page 1, Indicate the sponsor
- Question 1, correct NIH category III-D
- Question 3, spell out abbreviations for IP,RO,IC, AP/ML/DV,GC
- Question 4c, describe the agents that you plan to construct for this project.
- Question 7, the table is incomplete. What vectors will you use, and how will each individual vector be administered? Be as specific as possible for each vector that you will list.
- Question 7, include IP route of administration
- Question 7, table column 3, specify amount/titer as e14 viral particles
- Answer question 8b
- Answer question 9b and indicate the method how lots are determined to be replication incompetent, as there is no information in the safety information sheet from the vendor (Addgene)
- Safety Information Sheet: check NO, the virus does not integrate

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	No

Biohazard containment level X BL1 BL2 other:_____

Applicable Section of the NIH Guidelines: _____III-D _____

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

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

NOTE: Dr. Li arrived during the discussion for item 2.1 , there were 7 voting members present going forward.

2.2 **[2365126-1] Lung fibrosis metabolism - DNA**

PI: William Oldham

Reference Number: 503925

Submission Type: New Project
Review Type: Full Committee Review

Primary Reviewer: Jisu Li, Stephen Gregory

Discussion:

- Dr. Oldham provided a brief overview of the project. This proposal will use TGFb Adenovirus to induce pulmonary fibrosis in mice.
- Lab inspection for Claverick 401 is required.

Requested Corrections to application forms:

- Adenovirus construct list: please add a title to the document
- This form will serve as the lab inventory of BL-2 agents, as such, please make it clear on the spreadsheet which agents will be used for this project, which are on hand for other work, and which are proposed, but not are on hand yet.
- Please ensure that all agents listed in the Rec DNA application form are also on the excel spreadsheet
- Rec DNA application form:
- Question 3, Abbreviation: list all abbreviations including those listed in 4a (e.g. DAAO, BRD4, AlaDH) and TGFb from item 7.
- Question 4a, include TGFb if this is a recombinant adenovirus construct
- Question 7b, include a statement that breeding will be done off-site at CRL
- Question 10: Disposal of material: specify the use of freshly prepared 10% bleach to decontaminate material for > 10min before disposal
- Safety Information sheet (viral vector): it is not clear how many genes will be used, e.g. item 4a listed 3 genes, item 7 listed 1 gene, but the spread sheet includes 7 genes. Please clarify. Also, the gene functions listed in the spread sheet are not clear; e.g. the function of TGFb which is a growth factor and has oncogenic potential is not described.

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	No

Biohazard containment level BL1 X BL2 other:_____
Applicable Section of the NIH Guidelines: _____III-D _____

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

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

3 **Continuing Reviews DNA**

4 **Revisions- Full Board DNA**

5 **Administrative Check-In**

5.1 **[634896-25] Replication-Deficient adenovirus LC3**

PI: Ruhul Abid, MD, PhD

Reference Number: 018513, adenovirus, lentivirus
Submission Type: Continuing Review/Progress Report

Review Type: Administrative Review
Action: Acknowledged
Effective Date: October 20, 2025
Project Status: Active
Project Expiration: December 3, 2026

5.2 **[882725-24] Engineering exosomes loaded with Tat to reactivate latent HIV-1**
PI: Xiaoli Tang, Ph.D.
Reference Number: 007716, Lentivirus, AAV
Sponsor: Division of Infectious Diseases,Department of Medicine
Submission Type: Continuing Review/Progress Report

Review Type: Administrative Review
Action: Acknowledged
Effective Date: October 21, 2025
Project Status: Active
Project Expiration: November 5, 2026

5.3 **[1991530-10] Neurosurgery Core Laboratories Research**
PI: Margot Martinez-Moreno, PhD
Reference Number: 500223 lentivirus
Sponsor: Departmental funds
Submission Type: Continuing Review/Progress Report

Review Type: Administrative Review
Action: Acknowledged
Effective Date: October 23, 2025
Project Status: Active
Project Expiration: December 3, 2026

5.4 **[2043525-7] IBC Committee: LS-P-GO44479: A Phase II, Open-Label, Multicenter, Randomized Study of the Efficacy and Safety of Adjuvant Autogene Cevumeran plus Atezolizumab and mFolfirinox versus mFolfirinox Alone in Patients with Resected Pancreatic Ductal Adenocarcinoma**
PI: Alexander Raufi, MD
Reference Number: 502723
Sponsor: Genentech, Inc.
Submission Type: Continuing Review/Progress Report

Review Type: Administrative Review
Action: Acknowledged

Effective Date: October 23, 2025
Project Status: Active
Project Expiration: June 25, 2026

5.5 **[2261837-3] 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]**

PI: Maria Constantinou, MD
Reference Number: 501325 ceded to WCG
Sponsor: Replimune, Inc.
Submission Type: Amendment/Modification

Review Type: Administrative Review
Action: Acknowledged
Effective Date: November 3, 2025
Project Status: Active
Project Expiration: March 31, 2026
Next Report Due: April 1, 2026

6 **Expedited and Revision Reviews DNA**

6.1 **[634896-24] Replication-Deficient adenovirus LC3**

PI: Ruhul Abid, MD, PhD
Reference Number: 018513, adenovirus, lentivirus
Submission Type: Amendment/Modification

Review Type: Expedited Review
Action: Approved
Effective Date: October 27, 2025
Project Status: Active
Project Expiration: December 3, 2026
Remarks: personnel change

6.2 **[2237805-5] 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: Expedited Review
Action: Approved

Effective Date:	October 23, 2025
Project Status:	Active
Project Expiration:	October 6, 2027
Next Report Due:	October 1, 2026
Remarks:	updated IBs and consent forms

6.3 **[2237805-6] 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:	October 28, 2025
Project Status:	Active
Project Expiration:	October 6, 2027
Next Report Due:	October 1, 2026
Remarks:	administrative acknowledgement- clean copy of updated IB, previously reviewed with pkg 5

7 **Administrative Reviews DNA**

8 **Exempt DNA**

9 **Other Business DNA**

10 **End of DNA Business**

11 **Start of Hazard Business**

Dr. Dubielecka assumed responsibilities of the Chair

12 **New Studies Hazard**

12.1 **[1547161-4] Tamoxifen and Monocrotaline**

PI:	Olin Liang, PhD
Reference Number:	BLS 500520
Sponsor:	NIH, AHA
Submission Type:	Continuing Review/Progress Report
Review Type:	Full Committee Review
Primary Reviewer:	Patrycia Dubielecka-Szczerba

Discussion:

- This is the third-year renewal for the use of these two agents.
- Dr. Liang explained that Tamoxifen is used to induce Cre recombination in transgenic mice. Monocrotaline is used to induce pulmonary hypertension in animals.
- Housing and containment for Monocrotaline treated animals is not clear. Given that Monocrotaline is administered once weekly for multiple weeks, it is not clear whether animals remain in the disposable caging for the entire duration or whether they are moved back and forth after the initial 72 hours has passed. This point should be clarified.
- Dr. Liang is reminded that the PI is responsible for labeling cages appropriately once animals have been treated. CARE will provide cage cards for the PI/designee to place on the cages after dosing.
- It was noted that animals housed in the Barrier facility will remain in the same room when switching from disposable cages to standard cages after the hazard period has ended. It was noted that this may not be the case for animals housed in Coro West.
- Refresher training with the Chair regarding the use of these agents is required.

Requested Corrections to application forms:

- IBC application form: question 14c, expand to describe cage handling and decontamination for each agent, as separate responses.
- Question 14d, check YES if mice will be moved out of the Coro West hazard containment room to standard housing, and then answer questions 14(d) 1 and 2 regarding transport and decontamination.
- Hazards checklist: Animal Safety section, correct to state that cages will be changed 72 hours after the last dose
- Update all CRF references to CARE

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

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

13 **Expedited and Revision Reviews Hazard**

13.1 **[2370937-1] Tamoxifen**

PI:	William Oldham
Reference Number:	503725
Submission Type:	New Project
Review Type:	Expedited Review

13.2 **[2365681-2] Bleomycin**

PI:	William Oldham
Reference Number:	503125
Submission Type:	Response/Follow-Up
Review Type:	Expedited Review
Remarks:	corrections from pkg 1

13.3 **[2370268-2] Doxycycline**

PI:	William Oldham
Reference Number:	503325
Submission Type:	Response/Follow-Up
Review Type:	Expedited Review
Remarks:	corrections from pkg 1

13.4 **[1554168-3] Use of Human Cells in Immunodeficient Animals**

PI:	Olin Liang, Ph.D.
Reference Number:	BLS 500320
Sponsor:	Federal, foundation and departmental
Submission Type:	Continuing Review/Progress Report
Review Type:	Expedited Review

14 **Administrative Reviews Hazard**

15 **Other Business Hazard**

15.1 **Discussion Item- policy change - providing lists regarding which agents do and do not require IBC review**

Committee action: This item was tabled for discussion at a future meeting.

The meeting adjourned at 12:55 p.m.