



## Brown University Health - Institutional Biosafety Committee Minutes

January 5, 2026 Videoconference

Present: Dr. Jayasuriya, (Chairperson), Ms. Brilliant, Mr. Carrera, Dr. Gregory, Dr. Helwig, Dr. Jackson, Dr. Li, Mr. McEvoy, and Mr. O'Reilly

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

Investigators Submitting Applications for Review: Dr. Song and Dr. Koren

Guests: Dr. Song, Dr. Dhanabalan, and Dr. Roder

Support Staff: Ms. Poore

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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, Ms. Brilliant, Dr. Gregory, Dr. Helwig, Dr. Jackson, Dr. Li, 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 Minutes from 12/1/25**

Committee Action: The minutes were approved as submitted.

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

NOTE: Mr. O'Reilly joined the meeting after the vote was taken to approve the minutes.

### 2 **New Studies DNA**

#### 2.1 **[2398787-1] AAV8-D377Y-mPCSK9**

**PI:** Wenliang Song, MD

**Reference Number:** 504125

**Sponsor:** Internal

**Submission Type:** New Project

**Review Type:** Full Committee Review

Primary Reviewer: Cynthia Jackson, Chathuraka Jayasuriya

Presented by Dr. Song and Dr. Dhanabalan

Discussion:

- Dr. Song provided a brief overview of the project. The researchers will use AAV to overexpress PCSK9 to induce hypercholesterolemia in a double transgenic mouse model.
- A member asked how long AAV will remain in the mice. The researchers will check with

- the manufacturer.
- The researchers noted that the current plan is to administer AAV by tail vein injections but this may change if there are technical difficulties with that approach. The veterinarian recommended consulting with the veterinarians, as other routes of administration may distribute differently and may require different volumes. Another member noted that IV injection is the preferred route to achieve expression in the liver.
- The researchers verified that AAV constructs will be purchased and not made in the lab.
- Lab Safety and BL-2 inspections are required

Requested Corrections to application forms:

- Abstract, please add a brief statement detailing the goal or purpose of the study
- Application, top of page 2, include lab safety inspection date and BL-2 inspection date
- Item 1, check YES, this project does utilize recombinant or synthetic nucleic acid methodology
- Item 3, include TBG, and all other abbreviations
- Item 4c, include a statement that AAV will be purchased and not manufactured/made in your lab
- Item 7a, include the mouse strain in the table and update route if IV will not be used
- Please reach out to the Safety Office to schedule a lab safety inspection
- Please reach out to IBC Chairperson to schedule a BL-2 inspection

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.	Yes	X 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 and Dr. Jackson will serve as designated reviewers for the response.

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

### 3 Continuing Reviews DNA

#### 3.1 [640231-32] Assembly and Trafficking of Cardiac Voltage Gated Potassium Channels

**PI:** Gideon Koren, MD  
**Reference Number:** 021405, adenovirus, AAV  
**Sponsor:** NHLBI  
**Submission Type:** Continuing Review/Progress Report  
**Review Type:** Full Committee Review  
**Primary Reviewer:** Jisu Li, Stephen Gregory  
**Remarks:** third year renewal

Presented by Dr. Roder

Discussion:

- Dr. Roder provided an overview of the project which includes the use of AAV as gene therapy in transgenic rabbits at risk for sudden cardiac death. Dr. Roder noted that the team will try a

new route of administration in order to reduce the dose, as adverse effects have been seen under the current protocol.

- The animal work is now performed at Brown University.
- New AAV constructs and personnel have been added
- Reviewers noted that the application is very thorough. There were no concerns or comments.

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.	Yes	X No
Biohazard containment level <u>X</u> BL2 (adenoviral vectors in storage) <u>X</u> BL1 (AAV)		
Applicable Section of the NIH Guidelines: _____ III-D _____		

Committee Action: The committee voted to approve the submission as presented

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

#### 4 Revisions- Full Board DNA

#### 5 Administrative Check-In

#### 6 Expedited and Revision Reviews DNA

##### 6.1 [2365126-2] Lung fibrosis metabolism - DNA

**PI:** William Oldham  
**Reference Number:** 503925  
**Submission Type:** Response/Follow-Up

**Review Type:** Expedited Review  
**Action:** Approved  
**Effective Date:** December 18, 2025  
**Project Status:** Active  
**Project Expiration:** December 4, 2028  
**Next Report Due:** December 1, 2026  
**Remarks:** corrections from pkg 1

##### 6.2 [2383757-2] [IBC] Neural circuits underlying disorders of consciousness

**PI:** Athar Malik, MD, PhD  
**Reference Number:** 504025  
**Submission Type:** Response/Follow-Up

**Review Type:** Full Committee Review  
**Action:** Approved  
**Effective Date:** December 5, 2025

**Project Status:** Active  
**Project Expiration:** November 30, 2028  
**Next Report Due:** November 1, 2026  
**Remarks:** corrections from pkg 1

- 7 **Administrative Reviews DNA**
- 8 **Exempt DNA**
- 9 **Other Business DNA**
- 10 **End of DNA Business**
- 11 **Start of Hazard Business**
- 12 **New Studies Hazard**
- 13 **Expedited and Revision Reviews Hazard**
- 14 **Administrative Reviews Hazard**
- 15 **Other Business Hazard**

The meeting adjourned at 12:40 p.m.