Brown University Health - Institutional Biosafety Committee Minutes

May 4, 2026 12:00 PM

videoconference

Present: Dr. Jayasuriya, (Chairperson), Dr. Dubielecka-Szczerba (Vice Chairperson), Ms. Brilliant, Mr. Carrera (alternate for Mr. McEvoy), Mr. Dooner, Dr. Jackson, Dr. Gregory, (Associate Chair), Mr. McEvoy, and Ms. Tolbert

Absent: Dr. Helwig, Dr. Li, and Mr. O'Reilly

Investigators Submitting Applications for Review: Dr. Raufi, Dr. Lefort, 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 12:01 p.m.
The following voting members were present when the meeting began: Dr. Jayasuriya, Dr. Dubielecka-Szczerba, Ms. Brilliant, Mr. Carrera, Mr. Dooner, Dr. Gregory, and Ms. Tolbert

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.

The Committee welcomed Ms. Evelyn Tolbert as a new, non-affiliated member of the committee.

1 **Review of Previous Minutes: Minutes from 4/6/26**
Committee Action: The minutes were approved as submitted.

Vote: Number of members present 7, Approved 6, Opposed 0, Abstained 1 Recused 0

NOTE: Dr. Jackson joined the meeting after the vote was taken for the minutes. There were now 8 voting members in attendance.

2 **Start of DNA business**
3 **New Studies DNA**
4 **Continuing Reviews DNA**

4.1 **[2043525-8] 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:	Full Committee Review
Primary Reviewer:	Jisu Li, Cynthia Jackson

Remarks: Third year renewal

Presented by: Brittney Bernard

Discussion: Ms. Bernard provided a brief update, noting that 9 subjects have been enrolled into the study. As detailed in the progress report, 3 participants are off study treatment, 5 participants are in follow-up, and 1 participant is currently on active treatment. The study remains open to enrollment for new subjects. Ms. Bernard reported that study treatment appears to be well tolerated and that there have not been any adverse effects which were thought to be attributed to the investigational agent.

Requested corrections:

- Progress report, question 2, add NGS as in NGS analysis, and SAE
- Question 3a, 4th paragraph states: Autogene cevumeran for each patient consists of two drug products, each containing an RNA encoding up to 10 neoepitopes. Does this mean that 2 different sequences encoding up to a total of 20 neoepitopes will be administered? Here, a definition of other reagents injected, i.e., atezolizumab and/or mFolfirinox, would be helpful.
- Question 4, correct date when on-line training was completed for all staff listed and correct cut and paste formatting error for staff from Maria Andrea Monckeberg and the other pharmacists
- Please clarify the dose. On page 3 it states 0.01 mg/ml and on page 8 under administration to human subjects it states 0.05 mg/ml.

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:

Modified genetic materials will be used in humans	X Yes	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-C _____

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

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

NOTE: Mr. McEvoy joined the meeting after the vote was taken for Dr. Raufi's protocol. Mr. Carrera did not participate in the vote for any item after Mr. McEvoy joined the meeting. There were still 8 voting members in attendance.

4.2 **[639696-25] Mechanisms of Neutrophil Recruitment and Function**

PI: Craig Lefort, PhD

Reference Number: 003813, lentivirus, retrovirus

Sponsor: NIH, Departmental

Submission Type: Continuing Review/Progress Report

Review Type: Full Committee Review

Primary Reviewer: Stephen Gregory, Chathuraka Jayasuriya

Remarks: Third year renewal

Presented by: Dr. Lefort

Discussion: Dr. Lefort provided a brief overview, of his lab's work which looks at neutrophil biology and their function and role in disease. This project will include in vivo and in vitro studies, whereby cell lines will be modified and then transplanted into mice.

Requested corrections:

- Please provide a Safety Sheet for pLenti which will be used to create the new constructs referenced under question 3c.
- Progress report, question 9c, please add human modified cells which will be implanted into mice and expand the description of containment to include transport of BSL-2 reagents from the lab to the animal facility

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 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**

6.1 **[2261837-5] 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: 5013-25 ceded to WCG

Sponsor: Replimune, Inc.

Submission Type: Continuing Review/Progress Report

Review Type: Administrative Review

Action: Acknowledged

Effective Date: April 7, 2026

Project Status: Active

Project Expiration: March 14, 2028

Next Report Due: April 1, 2027

7 **Expedited and Revision Reviews DNA**

7.1 **[759582-31] Microbial Pathogenesis and Drug Discovery**

PI:	Gerard Nau, MD, PhD
Reference Number:	011715 adenovirus, lentivirus
Submission Type:	Response/Follow-Up
Review Type:	Expedited Review
Remarks:	requested corrections from pkg 30 continuing review

8 **Administrative Reviews DNA**
9 **Exempt DNA**
10 **Other Business DNA**
11 **End of DNA Business**

Dr. Dubielecka-Szczerba assumed responsibilities as Chair for this portion of the meeting.

12 **Start of Hazard Business**
13 **New Studies Hazard**

13.1 **[2424736-1] OXALIPLATIN**

PI:	Sendurai Mani
Reference Number:	500326
Submission Type:	New Project
Review Type:	Full Committee Review

Presented by Dr. Petra den Hollander

Discussion: The applications for all three agents, Oxaliplatin, Folinic Acid, and Irinotecan, were reviewed at the same time. Dr. Dubielecka-Szczerba will provide agent specific training.

Dr. den Hollander explained that these three agents are combined as the chemotherapy regimen Folfirinox which is used to treat pancreatic cancer. The researchers will test the agents in pancreatic cell lines alone and in combination with the intent of developing a less toxic treatment.

Dr. Dubielecka-Szczerba noted that powder should be handled under a chemical fume hood and solutions should be handled in a safety cabinet II. Dr. den Hollander explained that they will not be weighing the powder, the agent is reconstituted within the vial to reduce dust exposure.

The SDS sheet recommends storage at 4°C(in the dark) and to avoid aluminum contact.

Requested corrections:

- Application, question 2, please include the name of the commercial vendor
- Question 13, please answer NO, the agent is not infectious

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

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

13.2 **[2424742-1] FOLINIC ACID**

PI:	Sendurai Mani

Reference Number:	500426
Submission Type:	New Project
Review Type:	Full Committee Review
Primary Reviewer:	Patrycia Dubielecka-Szczerba

Presented by Dr. Petra den Hollander

Discussion: The applications for all three agents, Oxaliplatin, Folinic Acid, and Irinotecan, were reviewed at the same time. Dr. Dubielecka-Szczerba will provide agent specific training.

Dr. den Hollander explained that these three agents are combined as the chemotherapy regimen Folfirinox which is used to treat pancreatic cancer. The researchers will test the agents in pancreatic cell lines alone and in combination with the intent of developing a less toxic treatment.

Powder should be handled under a chemical fume hood and solutions should be handled in a safety cabinet II.

The SDS recommends storage at -20°C(in powder) or -80°C(in solvent).

Requested corrections:

- Application, question 2, please include the name of the commercial vendor
- Question 13, please answer NO, the agent is not infectious

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

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

13.3 **[2424744-1] IRINOTECAN**

PI:	Sendurai Mani
Reference Number:	500526
Submission Type:	New Project
Review Type:	Full Committee Review
Primary Reviewer:	Patrycia Dubielecka-Szczerba

Presented by Dr. Petra den Hollander

Discussion: The applications for all three agents, Oxaliplatin, Folinic Acid, and Irinotecan, were reviewed at the same time. Dr. Dubielecka-Szczerba will provide agent specific training.

Dr. den Hollander explained that these three agents are combined as the chemotherapy regimen Folfirinox which is used to treat pancreatic cancer. The researchers will test the agents in pancreatic cell lines alone and in combination with the intent of developing a less toxic treatment.

Powder should be handled under a chemical fume hood and solutions should be handled in a safety cabinet II.

The SDS recommends storing powder at -20°C or -80°C(in solvent) and protecting the material from light.

Requested corrections:

- Application, question 2, please include the name of the commercial vendor
- Question 13, please answer NO, the agent is not infectious

Committee Action: The committee voted to require modifications to secure approval. Dr. Dubielecka-

Szczerba will serve as the designated reviewer for the requested corrections.

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

14 **Expedited and Revision Reviews Hazard**
15 **Administrative Reviews Hazard**

16 **Other Business Hazard**

16.1 **BL-2 Safety Manual.** NIH guidelines stipulate that BSL-2 labs maintain a Safety Manual. Most of the items which would typically be included in a Safety Manual are maintained on-line, but not necessarily in one place for quick and easy reference. Ms. Poore populated the NIH sample Safety Manual template with Brown Health specific details. The draft version will be shared with the committee members for continued discussion next month.

The meeting adjourned at 12:31 p.m.