

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date: Tuesday, April 28, 2026
Time: 12:00 pm Pacific Time
Location: Zoom Teleconference
Institution: Children's Hospital of Orange County, Orange, CA
Principal Investigator: Quy Le, PhD
Project: Children's Hospital of Orange County, CHOC-202601
Meeting Type: Initial Review of Project and Site
Title: Development and pre-clinical testing of CAR-T cells in pediatric cancer

1. Call to order:

The Meeting was called to order at 12:00 pm Pacific Time.

2. Introductions and orientation:

Introductions were made and the Chair oriented members to the meeting procedures.

3. Declaration of quorum:

Four voting members were present, including one local member unaffiliated with the institution. Also present were the Principal Investigator, four Institutional Representatives, and IBC Services staff. The Chair declared that a quorum was present.

4. Conflict of Interest:

The Chair requested that voting members report any conflict of interest regarding this meeting. No conflicts of interest were reported.

5. Public posting:

An Institutional Representative confirmed that notice of the meeting was publicly posted. No public comments were received by the site or the Committee regarding this review.

6. Review of proposed research:

The Chair provided an overview of the project.

Points of Discussion:

1. The Principal Investigator stated that the same transfer plasmid backbone will be used to deliver transgenes to cells. The Committee recommended that descriptions of each vector, encoded transgenes, and their associated risks be provided to IBC Services.
2. The Committee noted that project documents refer to plasmids used to create lentiviral vectors and recommended that descriptions of these plasmids and vector system be provided to IBC Services.
3. The Committee noted that inadvertent creation of replication-competent lentivirus (RCL) is a risk associated with second-generation lentiviral systems. The Committee determined as a **Condition of Approval** that all newly created lentiviral vectors be tested for the presence of RCL using a validated assay and that an SOP documenting this testing procedure be created and provided to IBC Services.
4. The Principal Investigator confirmed that cells are modified using lentiviral vectors and that the work does not involve other vectors or genetic modification systems. The Committee recommended that a project-specific biohazard sign be created and provided to IBC Services.

7. Determination for biosafety level and period of IBC oversight:

The Committee determined that **BSL-2 containment facilities and practices** are required for all work with human cells and lentiviral vectors confirmed to be replication-incompetent.

The Committee determined that **BSL-2 containment facilities and practices with enhanced precautions** are required for lentiviral vector creation and RCL testing. Enhanced precautions include: use of double gloves, a biosafety cabinet, aerosol containment for centrifugation, and sharps avoidance

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The Committee determined that **ABSL-2 containment facilities and practices** are required for the administration of CAR T cells to mice and housing of mice after administration.

The Committee determined that IBC oversight will continue as long as the research is active at the site.

8. Vote on project:

The Committee voted for following determination on the Project:

	APPROVED
X	CONDITIONALLY APPROVED
	TABLED
	DISAPPROVED

For a vote of CONDITIONALLY APPROVED, the following condition must be met before the proposed research can proceed:

- a. All newly created lentiviral vectors be tested for the present of RCL using a validated assay and an SOP documenting this testing procedure be created and provided to IBC Services

DETERMINATION VOTE - YES: 4 NO: 0 ABSTAIN: 0

9. Review of Principal Investigator Qualifications:

The Committee reviewed and accepted the qualifications of the Principal Investigator.

10. Review of proposed facilities and practices:

The Chair provided an overview of the arrangement for the facilities and practices.

Points of Discussion:

1. The Biosafety Officer and Principal Investigator confirmed the following:
 - Lentiviral vectors and CAR T cells will be created withing Biological Safety Cabinets (BSCs) in negative pressure rooms on the 9th floor of the Southwest Tower
 - Mice will be handled in the Vivarium on the 6th floor of the Research Building, with cage washing on the 5th floor of the Research Building
2. The Committee recommended that Site Inspection Checklists and Photos of the Southwest Tower and Research Building be separated.
3. The Committee recommended that outdated photos be removed and that current site photos of handling locations for this research be provided to IBC Services.
4. The Committee recommended that details on centrifugation and aerosol containment methods be added to appropriate SOPs and provided to IBC Services.
5. An Institutional Representative stated that the BSCs used for the research were recently installed and certified. The Committee recommended that the BSC certification reports be provided to IBC Services when available.
6. The Committee noted the importance of verifying airflow prior to entering areas under negative pressure and recommended the institution explore the feasibility of implementing visual airflow indicators for these areas.
7. The Committee recommended that the Lentivirus Production and Titer SOP be revised to reflect the BSL-2 +/-Enhanced procedures noted in the Research Institute Safety Manual (page 111) and the IBC determination above.
8. The Committee noted that staff be aware of any lentivirus present in incubators and recommended that a lentivirus-specific incubator be used if available.
9. The Committee noted that plate sealers can be used to contain aerosols generated during spinoculation of T cells with lentiviral vectors and recommended that the CAR T Production SOP be revised if plate sealers will be used.

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10. The Committee recommended that a photo of the transport container used to move project-related materials within the institution be provided to IBC Services.
11. The Committee recommended that biohazard symbols be placed on all storage units, centrifuges, incubators, biohazardous waste containers, and BSCs containing infectious material.
12. The Committee recommended that all materials that come into contact with lentiviral vectors be decontaminated prior to removal from the BSC and noted that bleach or other effective disinfectants may be used.
13. The Committee recommended that a description of mice bedding changes, including decontamination procedures, be provided to IBC Services.
14. After discussion, the Committee opted to table the review pending receipt of materials noted above.

11. Site responsibilities:

The Chair reviewed training and communication requirements for maintaining IBC approval with the Institutional Representatives and the Principal Investigator.

12. Vote on the site:

The Committee voted for following determination on the Site:

	APPROVED
	CONDITIONALLY APPROVED
X	TABLED
	DISAPPROVED

DETERMINATION VOTE - YES: 4 NO: 0 ABSTAIN: 0

13. Advice to Institution: None.

14. Meeting adjourned: The meeting was adjourned at 1:15 pm Pacific Time.

15. Post-Meeting Notes: The condition of approval was met on the following date:

Resolution of condition for Conditional Approval:

Condition No.	Resolution	Date of Resolution	Approved by Chair
a.			

Documents Reviewed:

- Agenda
- Abstract and Project Description, dated 03-13-2026
- Bloodborne Pathogen Exposure Control Plan, dated 04-21-2025
- Exposure Control Plan, Lab Quality Management, dated 03-24-2025
- Exposure Control Plan, Specimen Collections, dated 03-12-2025
- Research Institute Safety Manual, dated 04-2026
- Site Map, dated 04-06-2026
- Site Inspection Checklist, BSL-1 and BSL-2, dated 03-17-2026
- Photos, dated 03-2026
- Biohazard Sign, BSL-2, dated 03-17-2026
- Bloodborne Pathogens Training Certification, dated 01-09-2026
- Lab Safety Training Certification, dated 01-13-2026
- BMT Lab Certifications, dated 03-10-2026
- Vivarium Certifications, dated 03-11-2026
- 4th Floor Certifications, dated 03-10-2026
- 5th Floor Certifications, dated 03-10-2026
- CAR-T In Vitro Assays SOP, updated 04-09-2026
- CAR-T In Vivo Assay SOP, updated 04-09-2026
- CAR-T Production SOP, updated 04-09-2026
- Lentivirus Production and Titer SOP, updated 04-09-2026

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Plasmids and Maps, received 04-10-2026
CV, Le, Q., received 03-05-2026