

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date: Wednesday, July 1, 2026
Time: 8:00 am 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 8:02 am 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 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.

The Chair and Principal Investigator provided an overview of materials that were provided in response to prior IBC recommendations.

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.

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 the Project:

The Committee voted for the following determination on the Project:

X	APPROVED
	CONDITIONALLY APPROVED
	TABLED
	DISAPPROVED

DETERMINATION VOTE - YES: 4

NO: 0

ABSTAIN: 0

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9. Review of proposed facilities and practices:

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

Points of Discussion:

1. The Committee recommended that containers used to transport lentiviral vectors and other project materials be labelled with the universal biohazard symbol, and that a confirmatory photo be provided to IBC Services.
2. An Institutional Representative confirmed that reusable lab coats are worn underneath disposable gowns. The Committee recommended that this information be added to all applicable SOPs.
3. An Institutional Representative confirmed that lentiviral vectors are not vortexed.
4. An Institutional Representative confirmed that the vented enclosure in Room 610A and the laminar flow hood in 610D are not used for this research. The Committee recommended that certification reports for both units be removed from project documentation.
5. An Institutional Representative confirmed that mouse cage tops are secured to prevent accidental dislodgement. The Committee recommended that item 25 on the Site Inspection Checklist be revised accordingly.
6. An Institutional Representative confirmed that a neutral disinfectant is used to decontaminate BSCs after use, and that bleach is used in vacuum aspirator waste flasks.
7. An Institutional Representative confirmed that both biohazard signs provided for review will be used for this research work. The sign listing emergency contact information and personal protective equipment will be posted on the exterior of the entry door, and a separate sign notifying staff of lentiviral work in progress will be posted on equipment as needed.
8. The Committee noted that aerosol-tight lids must be used during centrifugation procedures.
9. An Institutional Representative confirmed that mouse carcasses are stored in a freezer within the access-limited vivarium until disposal.

10. Site requirements:

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

11. Vote on the Site:

The Committee voted for the following determination on the Site:

X	APPROVED
	CONDITIONALLY APPROVED
	TABLED
	DISAPPROVED

DETERMINATION VOTE - YES: 4

NO: 0

ABSTAIN: 0

13. Advice to the Institution: None.

14. Meeting adjourned: The meeting was adjourned at 8:29 am Pacific Time.

15. Post-meeting notes: None.

Documents reviewed:

Agenda

Abstract and Project Description, dated 03-13-2026

Bloodborne Pathogen Exposure Control Plan, dated 04-21-2025

Bloodborne Pathogens Training Certification, dated 01-09-2026

Plasmids and Maps, updated 06-04-2026

Exposure Control Plan, Specimen Collections, dated 03-12-2025

Exposure Control Plan, Lab Quality Management, dated 03-24-2025

Research Institute Safety Manual, dated 04-2026

Site Map, 9th Floor, dated 06-26-2026

Site Map, 6th Floor, dated 06-26-2026

Photos, updated 06-04-2026

Site Inspection Checklist, BSL-1 and BSL-2, dated 06-26-2026

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Biohazard Sign, Lentivirus Work, received 06-10-2026
Biohazard Sign, BSL-2+, dated 05-05-2026
Vented Enclosure Certification, dated 03-11-2026
Laminar Flow Hood Certification, dated 03-11-2026
Biological Safety Cabinet Certification, 610C, dated 03-11-2026
Biological Safety Cabinet Certification, Room 9-210, dated 09-12-2025
ABSL-2 housing and husbandry SOP, received 06-10-2026
CAR-T In Vitro Assays SOP, received 06-10-2026
CAR-T In Vivo Assay SOP, received 06-10-2026
CAR-T Production SOP, received 06-10-2026
Lentivirus Production and Titer SOP, received 06-10-2026
CV, Le, Q., received 03-05-2026
Prior Meeting Minutes, Initial, dated 04-28-2026