

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date: Monday, August 24, 2026
Time: 9:00 am Pacific Time
Location: Zoom Teleconference
Institution: Children's Hospital of Orange County, Orange, CA
Principal Investigator: Jose E. Abdenur, MD
Project: Children's Hospital of Orange County, Derivation of human iPSCs
Meeting Type: Continuing Review of Project and Site
Title: Derivation of Human iPSCs

1. Call to order:

The Meeting was called to order at 9:01 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 two 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 stated that notice of the meeting was not publicly posted.

6. Approval of previous meeting minutes:

Minutes Approved - YES: 4 NO: 0 ABSTAIN: 0

7. Review of proposed research:

The Chair provided an overview of the project.

The Chair provided an overview of changes since the last review.

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

The Committee previously determined:

- **BSL-2** containment facilities and practices for work with Sendai virus vectors and cells transduced with Sendai virus vectors
- **ABSL-2** containment facilities and practices for administration of vector-transduced cells to mice
- **ABSL-1** containment facilities and practices plus additional precautions for housing of mice after administration of vector-transduced cells

For research requiring ABSL-1 plus additional precautions: Additional precautions include: PPE consisting of gloves and gown, annual bloodborne pathogen (BBP) training for all staff entering the facility, and hazard awareness signage. Hazard awareness signage must indicate the mice have been administered human cells, present a risk of BBP exposure, and that gloves and gown are required.

The Committee previously determined that **IBC oversight will continue as long as active research on the project continues.**

The Committee reaffirmed these determinations.

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9. Vote on project:

The Committee voted for following determination on the Project:

X	APPROVED
	CONDITIONALLY APPROVED
	TABLED
	DISAPPROVED

DETERMINATION VOTE - YES: 4

NO: 0

ABSTAIN: 0

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 Committee noted the difficulty in reviewing combined documents that pertain to multiple projects, either entirely or in part, and requested that the following documents be distinct for each project under IBC oversight:
 - a. Site Inspection Checklists
 - b. Site Photos
 - c. Site Maps
 - d. Biosafety Cabinet (BSC) Certification Reports
2. An Institutional Representative stated that many photos provided for IBC review are not current or are not relevant to the research being reviewed, and agreed to submit updated photographs of research areas used for each project, as well as those previously requested by the IBC (noted below).
3. The Committee noted the presence of food in a site photograph, but found it to be acceptable, as the area is an office separate from research areas.
4. The Committee noted a shallow box visible in a photo of the vivarium, and requested clarification regarding its relevance to the proposed research activities. An Institutional Representative confirmed that the item may be used for behavioral or balance testing but is not associated with the current research. The Committee recommended that the photograph be removed if it does not accurately represent the research activities under IBC review.
5. An Institutional Representative confirmed that biohazardous waste containers are not brought into BSCs to avoid cross-contamination, and that staff typically discard of materials into a small sealable container before discarding them into a nearby biohazardous waste container outside of the BSC. The Committee found this to be acceptable.
6. The Committee recommended that the liquid waste flasks in site photos be labeled with the universal biohazard symbol to ensure accurate hazard identification.
7. The Committee noted that certifications were not provided for certain BSCs used in the research. An Institutional Representative confirmed that all BSCs used for the research are properly certified, and agreed to provide all reports to IBC Services.
8. The Committee noted that the site had not addressed IBC recommendations made during previous reviews, and recommended that these items be addressed, confirmed, or resolved before the next IBC review:
 - a. The Committee recommended that the site map be accurately labelled with room numbers and associated biosafety levels.
 - b. The Committee recommended that photos of transport containers, if applicable, be provided to IBC Services.
 - c. An Institutional Representative stated that there are large biohazardous waste bins in all handling areas and that these are taken downstairs to a hallway for pickup by environmental services. The Committee recommended that a photo of this staging area be provided to IBC Services.
 - d. The Committee recommended that the disinfectant list in the Site Inspection Checklist (#21) be revised to indicate that 10% bleach and 70% ethanol are used.

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- e. The Committee recommended that all liquid vacuum traps contain an appropriate disinfectant and be fitted with an inline filter.
 - f. An Institutional Representative stated that animal bedding is changed in the animal housing rooms. The Committee recommended that autoclave bags be made available in each room for disposal of contaminated bedding.
 - g. The Committee recommended regular validation of cage washer function, including a water temperature of at least 180°F.
9. An Institutional Representative confirmed that the dump station is not located in the same room as the BSC and that an updated photograph of the room will be provided to IBC Services.
10. The Committee recommended that Site Inspection Checklist #12 be revised to remove the comment "Human cell culture utilizing recombinant lentiviruses" from the comment section.

11. Site responsibilities:

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

12. Vote on the site:

The Committee voted for following determination on the Site:

X	APPROVED
	CONDITIONALLY APPROVED
	TABLED
	DISAPPROVED

DETERMINATION VOTE - YES: 4

NO: 0

ABSTAIN: 0

13. Advice to Institution: None.

14. Meeting adjourned: The meeting was adjourned at 9:32 am Pacific Time.

15. Post-Meeting Notes: None.

Documents Reviewed:

Agenda

Updated Project Description, received 08-14-2024

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

Research Institute Safety Manual, dated 04-2026

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

Site Maps, Research Building, dated 06-26-2026

Site Inspection Checklist, BSL-1 and BSL-2, dated 06-11-2026

Photos, Research Building, dated 06-26-2026

Biological Safety Cabinet Certification, 4th Floor, dated 03-11-2026

Prior Meeting Minutes, Continuing, dated 08-19-2024