INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date:	**Wednesday, April 8, 2026**
Time:	10:00 am Mountain Standard Time
Location:	Zoom Teleconference
Institution:	Phoenix Children's Hospital, Phoenix, AZ
Principal Investigator:	**Celeste S.L. Cleveland, MD**
Protocol:	Cellectis, SA, **UCART22_01**
NCT Number:	NA
Meeting Type:	Initial Review of Protocol and Site
Title:	Open label dose-escalation and dose-expansion study to evaluate the safety, expansion, persistence and clinical activity of UCART22 (allogeneic engineered T-cells expressing Anti-CD22 Chimeric Antigen Receptor) in patients with relapsed or refractory CD22+ B-cell Acute Lymphoblastic Leukemia (B-ALL)

1. Call to order:

The Meeting was called to order at 10:00 am Mountain Standard Time.

2. Introductions and orientation:

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

3. Declaration of quorum:

Five voting members were present, including two local members unaffiliated with the institution. Also present were six 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 protocol.

The Chair provided an overview of the biosafety risk assessment for the protocol.

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

The Committee determined that **BSL-2 containment facilities and practices** are required for UCART22 since it consists of primary human cells modified using mRNA and a recombinant lentiviral vector.

The Committee determined that IBC oversight will continue for **3 months after the last subject's last dose of UCART22 locally**, provided that all biosafety criteria for study closure are also met.

8. Vote on the Protocol:

The Committee voted for the following determination on the Protocol:

X	APPROVED
	CONDITIONALLY APPROVED
	TABLED
	DISAPPROVED

DETERMINATION VOTE - YES: 5 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 Chair noted that storage and preparation occur at a separate facility not owned or directly affiliated with the Institution.
2. The Committee recommended that the biohazardous waste containers in the dosing rooms be labeled with biohazard symbols.
3. The Committee recommended that the large biohazardous waste storage container in the Soiled Holding Room not be overfilled and be lidded when not in use.
4. The Committee recommended that the Site Inspection Checklist (#2) be revised to indicate that study agent-specific Biosafety SOP training is logged.
5. An Institutional Representative confirmed that the Biological Safety Cabinets (BSCs) listed in the comments of Site Inspection Checklist (#11) are located in the Pharmacy at Vitalant Cell Therapy Lab.
6. The Committee recommended that the Site Inspection Checklist (#14) be revised to indicate which protocols use reusable sharps.
7. The Committee recommended that the Site Inspection Checklist (#19) be revised by removing 70% IPA as an available decontaminant.
8. The Committee noted that specific training requirements for IATA federal regulations are missing from the providing shipping training certification. The Committee recommended that all future IATA Shipping Certifications submitted for IBC review include this information.
9. An Institutional Representative stated that handwashing sinks are available in the dosing rooms, as well as in the hallway just outside of the dosing rooms.
10. The Committee recommended that the Institution follow up with IBC services on the type of transport container that is used for study agent transport and noted that it should be hard-sided, lidded, and labelled with a biohazard symbol. The Committee also recommended that an updated photo of the transport container be provided to IBC Services.
11. The Committee recommended that an eyewash sign be placed above the sink in the IP Room at the Vitalant Cell Therapy Lab to clearly indicate the location of the plumbed eyewash station.
12. The Committee noted that it is not best safety practice for a plumbed eyewash to be attached to a “dirty sink” as indicated in the site photos for the Pharmacy at the Vitalant Cell Therapy Lab.

11. Site requirements:

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

12. Vote on the Site:

The Committee voted for the following determination on the Site:

X	APPROVED
	CONDITIONALLY APPROVED
	TABLED
	DISAPPROVED

DETERMINATION VOTE - YES: 5 NO: 0 ABSTAIN: 0

13. Advice to the Institution: None.

14. Meeting adjourned: The meeting was adjourned at 10:21 am Mountain Standard Time.

15. Post-meeting notes: None.

Documents reviewed:
Agenda
Protocol, Version 9.1, dated 01-23-2026
Investigator's Brochure, Version 7.0, dated 07-23-2025

Cell Therapy Manual, Version 8.0, dated 04-09-2025
Biological Risk Assessment and Summary, dated 03-24-2026
Site Map, Phoenix Children's Hospital, 7th Floor, dated 12-09-2025
Site Map, Vitalant Cell Therapy Lab, dated 02-07-2024
Site Inspection Checklist, dated 11-07-2025, updated 04-06-2026
Photos, Phoenix Children's Hospital, dated 04-01-2026
Photos, Vitalant Cell Therapy Lab, dated 04-06-2026
Biohazard Sign, UCART22, dated 04-01-2026
Biological Safety Cabinet Certifications, Vitalant, dated 07-03-2025, 08-21-2025
SOP, Biosafety for UCART22, dated 04-06-2026
Training, Shipping Certification, expires 01-22-2028
CV, Cleveland, C., signed 07-26-2024