

# INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

## MEETING MINUTES

**Meeting Date:** Friday, October 24, 2025  
**Time:** 11:00 am Mountain Time  
**Location:** Zoom Teleconference  
**Institution:** Intermountain Health - Salt Lake City, Salt Lake City, UT  
**Principal Investigator:** Brad Hunter, MD, MPH  
**Protocol:** Lyell Immunopharma, Inc., LYL314-102  
**NCT Number:** NCT05421663  
**Meeting Type:** Initial Review of Protocol and Site  
**Title:** A phase 3 randomized controlled trial of Rondecabtagene Autoleucel, a dual-targeting CD19/CD20 CAR T-Cell product candidate, versus investigator's choice of CD19 CAR T-Cell therapy in patients with relapsed or refractory large B-Cell Lymphoma in the second-line setting (PiNACLE-H2H)

### 1. Call to order:

The Meeting was called to order at 11:00 am Mountain 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 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 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 LYL314, since it consists of autologous T cells modified by a recombinant, replication-defective lentiviral vector.

The Committee determined that IBC oversight will continue for **3 months after the last subject's last dose of LYL314 locally**, provided all other criteria for study closure are 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.

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### **10. Review of proposed facilities and practices:**

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

#### **Points of Discussion:**

1. An Institutional Representative confirmed that prefilled disposable eyewash bottles are not available in the preparation/dosing rooms but there is a plumbed eyewash station located on the same floor that staff could reach within 10 seconds in the event of an eye exposure. The Committee found this to be acceptable.
2. The Committee recommended that the [REDACTED] site map be updated to indicate the location of the plumbed eyewash station.
3. The Committee discussed the use of 10% bleach solution, noting that bleach is considered corrosive and recommended that staff wear eye protection when preparing the solution. The Committee also recommended that 10% bleach solution only be used for clean-up of spills in the water bath.
4. The Committee recommended that PDI Super Sani-Cloth wipes be used for clean-up of large spills instead of bleach and that Section 5.1.4b of the Biosafety SOP be revised to indicate this.
5. The Committee recommended that Biosafety SOP Section 3.5 be revised to replace "luer port" with "luer lock port."

### **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:

### **13. Advice to the Institution:** None.

### **14. Meeting adjourned:** The meeting was adjourned at 11:19 am Mountain Time.