

# INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

## MEETING MINUTES

**Meeting Date:** Wednesday, June 4, 2025  
**Time:** 9:00 am Central Time  
**Location:** Zoom Teleconference  
**Institution:** Northwestern University, Chicago, IL  
**Principal Investigator:** Devalingam Mahalingam, MD, PhD  
**Protocol:** Imugene Limited, CF33-CD19-101  
**NCT Number:** NCT06063317  
**Meeting Type:** Continuing Review of Protocol and Site  
**Title:** A Phase I, Dose Escalation and Dose Expansion, Safety and Tolerability Study of onCARlytics (CF33-CD19), Administered Intravenously or Intratumorally in Combination with Blinatumomab in Adults with Advanced or Metastatic Solid Tumors (OASIS)

### 1. Call to order:

The Meeting was called to order at 9:00 am Central Time.

### 2. Introductions and orientation:

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

### 3. Declaration of quorum:

Six voting members were present, including two local members unaffiliated with the institution and the Institution's Biosafety Officer. 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:

The Biosafety Officer confirmed that notice of the meeting was publicly posted. No public comments were received by the site or the Committee regarding this review.

### 6. Approval of previous meeting minutes:

Minutes Approved - YES: 6                      NO: 0                      ABSTAIN: 0

### 7. Review of proposed research:

The Chair provided an overview of the protocol and status of the study.

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 that **BSL-2 containment facilities and practices** are required for CF33-CD19, since it consists of an oncolytic orthopox virus administered in a clinical setting. The Committee reaffirmed this determination.

The Committee previously determined that IBC oversight will continue for **6 months after the last subject's last dose of CF33-CD19 locally**, provided that other biosafety criteria for study closure are met. The Committee reaffirmed this determination.

### 9. Vote on the Protocol:

The Committee voted for the following determination on the Protocol:

X	APPROVED
	CONDITIONALLY APPROVED
	TABLED
	DISAPPROVED

DETERMINATION VOTE - YES: 6                      NO: 0                      ABSTAIN: 0

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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. The Committee discussed the site preparation change which moved vortexing of study agent vials from inside the biological safety cabinet (BSC) or Bioquell compounding aseptic containment isolator (CACI) to the countertop. The Committee had concerns with vortexing outside of primary containment due to the nature of the study agent.
2. The Committee recommended that vortexing be performed inside the BSC or CACI and that Biosafety SOP Section 5.4 be revised to reflect this.
3. An Institutional Representative could not confirm whether priming of the dosing needle prior to intratumoral injection takes place inside the BSC/CACI or at the subject's bedside. The Committee recommended the site confirm where and how priming occurs, and that Biosafety SOP Section 5.5 be revised accordingly.
4. The Biosafety Officer confirmed that the BSCs and CACI had recently been recertified but that the vendor had not yet provided the current certification reports. The Committee recommended that current certification reports be provided to IBC Services when available.
5. The Committee expressed concern regarding the lack of a current CACI certification report for review given that there has previously been much discussion regarding the details provided in this report. The Biosafety Officer stated that it typically takes the vendor about one month to provide the report after the unit has been certified.
6. The Committee recommended that the Institution request that the vendor provide certification reports on a more timely basis (ideally, within one week) in the future.
7. The Committee requested that the current CACI certification report be provided to them for review once it is received by IBC Services and recommended that additional studies at the Institution using the CACI not be scheduled for review until the current CACI certification report is received.
8. The Committee noted that the CACI serial number listed on the HEPA filter integrity testing report does not match the serial number listed on the certification report. The Committee recommended that the Institution confirm the correct serial number and ensure all reports and site documents match and reflect the correct number.
9. The Committee had previously discussed concerns regarding the ease with which the CACI can be switched between positive and negative pressure and had recommended that a policy should be in place for staff to ensure that the CACI is set to negative pressure when preparing biological agents. The Committee recommended that this policy be provided to IBC Services.
10. An Institutional Representative confirmed that educational material with post-dosing instructions is provided to subjects and their caregivers. The Committee recommended that this information be provided to IBC Services.
11. The Committee recommended that the Biosafety Officer follow up with staff to confirm what color paper the Biohazard Sign is printed on.
12. An Institutional Representative could not confirm that the main hospital emergency phone number, which is answered 24/7, is answered by a person who is able to route this call to the appropriate study staff member.

### **11. Site requirements:**

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

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### **12. Vote on the Site:**

The Committee voted for the following determination on the Site:

X	APPROVED
	CONDITIONALLY APPROVED
	TABLED
	DISAPPROVED

DETERMINATION VOTE - YES: 6                      NO: 0                      ABSTAIN: 0

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

**14. Meeting adjourned:** The meeting was adjourned at 9:31 am Central Time.