INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date:	**Wednesday, June 18, 2025**
Time:	8:00 am Pacific Time
Location:	Zoom Teleconference
Institution:	Swedish Health Services, Seattle, WA
Principal Investigator:	**Fengting Yan, MD, FACP**
Protocol:	Calibr-Skaggs Institute for Innovative Medicines, **CBR-sCAR461-3001**
NCT Number:	NCT06878248
Meeting Type:	Initial Review of Protocol and Site
Title:	A Phase 1, Open-Label, Dose-Escalation Study Evaluating the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of the Combination of CLBR001, an Engineered Autologous T Cell Product, and ABBV-461, an Antibody-Based Biologic, in Subjects with Locally Advanced or Metastatic Breast Cancer

1. Call to order:

The Meeting was called to order at 8:17 am Pacific 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 eleven 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 CLBR001, since it consists of autologous T cells modified by a lentiviral vector.

The Committee determined that IBC oversight will continue for **3 months after the last subject's last dose of CLBR001 locally**, provided that other 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. An Institutional Representative confirmed that a phone number for the Principal Investigator was provided to IBC Services just prior to the meeting. The Committee recommended that this number be added to the Biohazard Sign.
2. The Committee noted that as previously discussed for other studies at the Institution, the [redacted] biohazardous waste storage room photo shows numerous items stored around the sink and on top of the sharps container. An Institutional Representative confirmed that these items have been removed, and an updated photo was provided to IBC Services just prior to the meeting.
3. An Institutional Representative confirmed that study staff receive annual bloodborne pathogens and biosafety SOP training.
4. The Committee discussed that the locations listed on page 3 of the Site Inspection Checklist are reflective of multiple protocols and that the corresponding Biosafety SOPs define the specific locations where research activities occur for that protocol.

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 8:24 am Pacific Time.