

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date: Tuesday, December 30, 2025
Time: 8:00 am Pacific Time
Location: Zoom Teleconference
Institution: Swedish Health Services, Seattle, WA
Principal Investigator: Swathi Namburi, MD
Protocol: Nexcella, Inc., **NXC-201-AL-001**
NCT Number: NCT06097832
Meeting Type: Continuing Review of Protocol and Site
Title: Phase 1b/2 Study of NXC-201 for the Treatment of Patients with Relapsed or Refractory AL Amyloidosis [BEXICART-2]

1. Call to order:

The Meeting was called to order at 8:00 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 five 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. 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 protocol and status of the study.

The Chair noted 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 NXC-201 since it consists of primary human cells modified with a recombinant retroviral vector. The Committee reaffirmed this determination.

The Committee previously determined that IBC oversight will continue for **3 months after the last subject's last dose of NXC-201 locally**, provided all other biosafety criteria required for study closure are also 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: 4

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. An Institutional Representative agreed to confirm if the [REDACTED] is locked since this room is located in an area not restricted to the public. If this room is not locked, the Committee recommended that a lock be installed on this door to ensure this area is restricted to only staff members.
2. The Committee recommended that Biosafety SOP for Genetically Modified Human Cells Section 5.1 be revised to add another subsection noting how soiled linens will be disposed of in the event of a spill (e.g., In the event of a spill on bed linens, contaminated soiled linens will be disposed of into a biohazardous waste container).
3. The Committee recommended that a biohazard symbol/sign be placed on the storage refrigerator when the study agent is in storage.

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: 4

NO: 0

ABSTAIN: 0

13. Advice to the Institution: None.

14. Meeting adjourned: The meeting was adjourned at 8:10 am Pacific Time.