

INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date: Tuesday, September 2, 2025
Time: 12:00 pm Arizona Time
Location: Zoom Teleconference
Institution: HonorHealth, Scottsdale, AZ
Principal Investigator: Justin Moser, MD
Protocol: BioEclipse Therapeutics, CRX100-001
NCT Number: NCT04282044
Meeting Type: Continuing Review of Protocol and Site
Title: A Phase 1 Study of the Safety and Efficacy of CRX100 as Monotherapy and in Combination with Pembrolizumab in Advanced Solid Malignancies

1. Call to order:

The Meeting was called to order at 12:13 pm Arizona 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 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. 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 provided an overview of changes since the last review.

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

The Committee determined that **BSL-2 containment facilities and practices** are required for CRX100, since it consists of primary human cells genetically modified with an attenuated vaccinia virus. The Committee reaffirmed this determination.

The Committee previously determined that IBC oversight would continue for **3 months after the last subject's last dose of CRX100 locally**, provided all other 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: 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. The Committee noted that the IATA/Training Shipping Certification for a study staff member expires in September 2025. The Committee recommended that the staff member complete training prior to the expiration date and the certification be provided to IBC Services.
2. The Committee noted that the Biological Safety Cabinet (BSC) is due for recertification this month and recommended that the newer certification be submitted to IBC Services when it becomes available from the certifying company.
3. An Institutional Representative confirmed that plumbed eyewashes are flushed on a weekly basis. The Committee recommended that Site Inspection Checklist Item 22 be revised to reflect this information.
4. The Committee recommended that an eyewash sign be placed on the wall above plumbed eyewash in the [REDACTED].
5. The Committee recommended that the [REDACTED] be labeled with a biohazard symbol and recommended that a new photo of this be submitted to IBC Services.
6. The Committee noted that the study agent consists of a mixture of human cells and live vaccinia virus. However, this virus is based on an attenuated vaccinia virus and the risk of horizontal transmission is expected to be low. The Committee noted that the Institution could consider covering intravenous infusion sites for a period of time after dosing to further minimize the risk of horizontal transmission of the study agent.

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 12:23 pm Arizona Time.