INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

MEETING MINUTES

Meeting Date:	**Wednesday, December 17, 2025**
Time:	11:00 am Eastern Time
Location:	Zoom Teleconference
Institution:	Accellacare - Wilmington, Wilmington, NC
Principal Investigator:	**Kevin D. Cannon, MD**
Protocol:	BioNTech SE, **BNT163-01**
NCT Number:	NCT05432583
Meeting Type:	Continuing Review of Protocol and Site
Title:	Phase I, randomized, observer-blinded, 3-part, dose escalation and expanded safety and dose evaluation trial to evaluate the safety, tolerability, and immunogenicity of an investigational prophylactic vaccine for the prevention of genital lesions caused by HSV-2 and potentially HSV-1

1. Call to order:

The Meeting was called to order at 11:01 am Eastern 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 was one 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 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: 5 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-1 containment facilities and practices plus Standard Precautions** are required for BNT163, since it consists of an LNP-encapsulated mRNA administered by injection in a clinical setting. 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 BNT163 locally**, provided that all biosafety criteria 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: 5 NO: 0 ABSTAIN: 0

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 recommended that Site Inspection Checklist, Item 21 be revised to indicate that staff members use hand sanitizer prior to exiting the room when a sink is not available.
2. The Institutional Representative confirmed that the -20°C freezer in the Storage Room is not used to store the study agent.
3. The Institutional Representative confirmed that biohazardous waste containers used to dispose of personal protective equipment (PPE) are hard-sided and have a lid.
4. The Institutional Representative confirmed that only closed red bags and sharps containers are disposed of in the open-topped biohazardous waste boxes. The Committee determined this to be acceptable.
5. The Institutional Representative confirmed that the Biohazard Sign is posted at the entrance to areas where study agent is handled.

11. Site requirements:

The Chair reviewed training and communication requirements for maintaining IBC approval with the Institutional Representative.

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 11:16 am Eastern Time.