

# INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

## MEETING MINUTES

**Meeting Date:** Friday, August 22, 2025  
**Time:** 11:00 am Central Time  
**Location:** Zoom Teleconference  
**Institution:** Decatur Memorial Hospital, Decatur, IL  
**Principal Investigator:** James L. Wade, III, MD  
**Protocol:** BioNTech SE, BNT122-01  
**NCT Number:** NCT04486378  
**Meeting Type:** Continuing Review of Protocol and Site  
**Title:** A multi-site, open-label, Phase II, randomized, controlled trial to compare the efficacy of RO7198457 versus watchful waiting in resected, Stage II (high risk) and Stage III colorectal cancer patients who are ctDNA positive following resection

### 1. Call to order:

The Meeting was called to order at 11:01 am Central 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 two Institutional Representatives, the Principal Investigator 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 Principal Investigator and 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 RO7198457, since it consists of liposome-encapsulated mRNA molecules. 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 RO7198457 locally**, provided that other 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: 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 Principal Investigator and Institutional Representatives confirmed that plumbed eyewashes are flushed on a weekly basis and agreed to confirm that a log of the flushing is maintained.
2. The Committee recommended that the Institution's name in the Site Inspection Checklist be revised from "████████████████████" to "Decatur Memorial Hospital".
3. The Committee noted that the Site Inspection Checklist lists two Biological Safety Cabinets that may be used, but that only one certification was available for review. The Committee recommended that the other BSC Certification for the BSC with the serial number ██████████ be submitted to IBC Services.
4. The Committee recommended that an updated photo showing the biohazardous waste containers in the dosing area be submitted to IBC Services.

### **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 11:22 am Central Time.