

# INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

## MEETING MINUTES

**Meeting Date:** Monday, July 21, 2025  
**Time:** 12:00 pm Eastern Time  
**Location:** Zoom Teleconference  
**Institution:** University of North Carolina at Chapel Hill, Chapel Hill, NC  
**Principal Investigator:** John Buse, MD, PhD  
**Protocol:** GentiBio, GNTI-122-T1D-1001  
**NCT Number:** NCT06919354  
**Meeting Type:** Initial Review of Protocol and Site  
**Title:** A Phase 1, Single Dose, Open-Label Study of GNTI-122 in Adults With Recently Diagnosed Type 1 Diabetes (T1D)

### 1. Call to order:

The Meeting was called to order at 12:01 pm Eastern Time.

### 2. Introductions and orientation:

Introductions were made and the Chair oriented members to the meeting procedures.

### 3. Declaration of quorum:

Seven voting members were present, including three local members unaffiliated with the institution and the Institution's Associate Biosafety Officer. Also present were the Principal Investigator, three 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.

### Point of Discussion:

1. The Principal Investigator noted that rapamycin is used to provide an interleukin 2 (IL-2)-like signal which helps with proliferation and survival of the T cells.

### 7. Determination for biosafety level and period of IBC oversight:

The Committee determined that **BSL-2 containment facilities and practices** are required for GNTI-122, since it consists of autologous T cells modified using CRISPR/Cas9 and recombinant AAV vectors.

The Committee determined that IBC oversight will continue for **3 months after the last subject's last dose of GNTI-122 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: 7

NO: 0

ABSTAIN: 0

### 9. Review of Principal Investigator qualifications:

The Committee reviewed and accepted the qualifications of the Principal Investigator.

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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 confirmed that the study agent is transported in a liquid nitrogen dewar or the sealed cryoshipper from the [REDACTED] to the subject's bedside. The Committee recommended that the study agent be removed from the storage container as far away from the subject as possible.
2. An Institutional Representative confirmed that a water bath is transported on a mobile cart to the subject's bedside and the study agent is thawed, prepared, and dosed in the same room.
3. The Committee recommended that a photo of the preparation area, showing how it is set up for study agent activities, be provided to IBC Services.
4. The Associate Biosafety Officer confirmed that the cardboard biohazardous waste boxes in the [REDACTED] are collected by [REDACTED] and that prior to transport to the biohazardous waste storage area, the red bag inside the box is tied off and the lid is sealed.

### **11. Site requirements:**

The Chair reviewed training and communication requirements for maintaining IBC approval with the Principal Investigator and 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: 7

NO: 0

ABSTAIN: 0

### **13. Advice to the Institution:** None.

### **14. Meeting adjourned:** The meeting was adjourned at 12:21 Eastern Time.