

# INSTITUTIONAL BIOSAFETY COMMITTEE REVIEW

## MEETING MINUTES

**Meeting Date:** Wednesday, December 17, 2025  
**Time:** 9:00 am Central Time  
**Location:** Zoom Teleconference  
**Institution:** Northwestern University, Chicago, IL  
**Principal Investigator:** Satish Nadig, MD, DPhil, FACS  
**Protocol:** United Therapeutics Corp., GPK-KF-101  
**NCT Number:** NCT06878560  
**Meeting Type:** Initial Review of Protocol and Site  
**Title:** EXPAND: A Prospective Study to Evaluate the Safety and Efficacy of the 10 GE Xenokidney in Patients with End-stAge ReNal Disease (ESRD)

### 1. Call to order:

The Meeting was called to order at 9:01 am Central Time.

### 2. Introductions and orientation:

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

### 3. Declaration of quorum:

Six voting members were present, including two local members unaffiliated with the institution and the Institution's Biosafety Officer. Also present were nine 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 Committee noted that the Investigator's Brochure indicates that donor kidneys are tested for 18 porcine pathogens, but information on the sponsor's website indicates that over 40 different pathogens are screened. The Committee noted that the sponsor has enacted enhanced safety and security precautions at the facility that houses the donor animals.

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

The Committee determined that **Biosafety Level 2 containment facilities and practices** are required since the 10 GE Xenokidney consists of a whole kidney sourced from a pig genetically engineered using CRISPR-based genome editing and it is transplanted in a surgical setting.

The Committee determined that IBC oversight will continue for **6 months after the last subject's last dose of the 10 GE Xenokidney 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: 6

NO: 0

ABSTAIN: 0

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### **9. Review of Principal Investigator qualifications:**

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

### **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 extra pig organ will be packaged and shipped back to the sponsor after the transplant surgery. The Committee recommended that Biosafety SOP Section 6.1 be revised to state "...the organ will be prepared for shipping back to the sponsor using a provided lab kit."
2. The Committee recommended that a subsection be added to Biosafety SOP Section 7 with details about the Institution's plan or policy in the event the donor organ is accidentally mishandled.
3. The Committee noted that staff members who come into direct contact with the donor kidney must be consented to participate in a porcine pathogen surveillance program and that staff members who do not come into direct contact have the option to consent to participate in the surveillance program.
4. The Committee recommended that the Biohazard Sign be updated to add the following: "Special Precautions: Study staff who come into direct contact with the 10 GE Xenokidney must consent to participate in a porcine pathogen surveillance program and staff members who do not come into direct contact have the option to consent to participate in the surveillance program."
5. The Committee noted that it appears that the entrance to the [REDACTED] on the [REDACTED] [REDACTED] are located do not appear to be labeled with a biohazard symbol. The Committee recommended that these rooms be labeled with biohazard signage or a symbol when biohazardous waste generated in this study is in storage.
6. The Committee discussed the red biohazard bag in an [REDACTED] in the Photos document and noted that if saturated materials are placed in this bag, there is a risk that the bag could leak onto other surfaces since it is not within a secondary container. An Institutional Representative confirmed that red biohazard bags will be placed in secondary containment in the [REDACTED].
7. The Biosafety Officer noted that biohazardous liquid waste generated during surgeries is disposed of through a house system.
8. The Committee noted that it appears some biohazardous waste and sharps and sharps containers in an [REDACTED] are overflowing as shown in the Photos document. The Committee recommended that sharps containers not be overfilled.
9. The Committee discussed the waste containers as shown in the Photos document and noted that it appears the black container is lined with a plastic bag. An Institution Representative confirmed that this black container is only used for chemo hazardous waste, and is not used to dispose of sharps.
10. The Committee recommended that biohazardous waste containers either be a red color, or that they have a visible biohazard symbol on them.
11. An Institutional Representative confirmed that the Institution's [REDACTED] approved this study.

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

The Chair reviewed training and communication requirements for maintaining IBC approval with the Biosafety Officer and 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: 6

NO: 0

ABSTAIN: 0

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

**14. Meeting adjourned:** The meeting was adjourned at 9:30 am Central Time.