# MINUTES
# INSTITUTIONAL BIOSAFETY COMMITTEE
# DATE: December 12, 2025

**Attendance:** Total Attending: 10 **Voting Members Present**: 7

**Called to Order**: 10:03 a.m.

| Name | Expertise | Present |
|---|---|---|
| Linda Cassidy, MS | Non-Voting Member | X |
| Sue Gotta, MS | rDNA; Select Agents | X |
| Gerald Grunwald, PhD | rDNA; Biochemistry; Cellular & Developmental Biology | X |
| Douglas C. Hooper, PhD | rDNA; Immunology; Gene Transfer | |
| Botond Igyarto, PhD | Microbiology | X |
| Loretta Kelly, Esq. | Non-affiliate Community Member | X |
| Kathleen "Kitty" Kono | Non-Affiliate Community Member | |
| Phil LaTourette, DVM | Laboratory Animal Sciences | X |
| Sara Meyer, PhD | Cancer Biology | X |
| Fabienne Paumet, PhD | Cellular Biology & Biochemistry | |
| Drake Stierman | Non-Voting Member | X |
| Yuri Sykulev, PhD | Microbiology | X |
| Megan Watson | Non-Voting Member | X |

**MINUTES REVIEWED:**
Minutes November 2025 meeting were presented for review.

Motion to Approve: Phil LaTourette
Seconded: Botond Igyarto
Total = 7; For-7, Opposed-0, Abstained-0

**NEW PROTOCOLS:**

1. **Principal Investigator I.T.** IBC Control# 25-11-988 "*A Phase 1 Study of FT819 in B-cell Mediated Autoimmune Diseases"*

**Summary**:
- This research involves a new treatment, FT819, for illnesses involving B-cell mediated autoimmune diseases.
- This is a human gene therapy study.
- The principal risk identified was:
  - CAR-T cells
- Containment has been set to BSL-2.

**Committee Review:**
- This protocol was reviewed under NIH Category C.
- The risks were adequately identified by the Principal Investigator and appropriate mitigation was described in the protocol**.**
- Clarifications were requested.
- A motion was made and seconded to provisionally approve this protocol. The motion was unanimously approved.

2. **Principal Investigator S.W.** IBC Control# 25-11-996

**Summary:**

- This research is trying to understand how infections, from various viruses, and inflammation in the body affect the brain.
- The study includes in vivo and in vitro research.
- The principal risks identified were the use of:
  - SARS-CoV-2
  - Influenza
  - Rabies
- Containment has been set to BSL2 and ABSL2 for one of the influenza viruses. For the remaining viruses the containment level has been set to BSL3 and ABSL3.

**Committee Review:**

- This protocol did not involve either recombinant or synthetic DNA**.**
- The risks were adequately identified by the Principal Investigator and appropriate mitigation was described in the protocol.
- Clarifications were requested.
- A motion was made and seconded to provisionally approve this protocol. The motion was unanimously approved.

*3.* **Principal Investigator M.Z.** IBC Control# 25-11-993 *"Endocardial Delivery of XC001 Gene Therapy for Refractory Angina Coronary Treatment: A 26-Week (with 26 Week Extension) Phase 2b Randomized, Multi-Center, Double-Blind, Sham Controlled Study to Evaluate Efficacy and Safety (The EXACT-2 Trial)"*

**Summary:**

- The purpose of this research is to determine the efficacy of the experimental drug called XC001 in patients with angina caused by coronary artery disease who have no other treatment options.
- This is a human gene therapy study.
- The principal risk identified was:
  - Adenovirus
- Containment has been set to BSL-2.

**Committee Review:**

- This protocol was reviewed under NIH Category C.
- The risks were adequately identified by the Principal Investigator and appropriate mitigation was described in the protocol.
- Clarifications were requested.
- A motion was made and seconded to provisionally approve this protocol. The motion was unanimously approved.

*4.* **Principal Investigator S.M.** IBC Control# 25-11-997 "*A Phase 1/2 Dose-Finding and Pharmacokinetic Study of Intravenous VNX-202 Gene Therapy in Patients with HER2-Positive Cancer with Prior Systemic and/or Local Treatment at Risk of Relapse/Metastasis (SENTRY-HER2)"*

**Summary:**

- The overall goal of the study is to determine whether this one-time gene therapy, VNX-202, can be given safely, how the body responds to it, and whether it shows early signs of helping control or reduce HER2-positive cancer.
- This is a human gene therapy study.
- The principal risk identified was:

  - AAV
- Containment has been set to BSL-2.

**Committee Review:**

- This protocol was reviewed under NIH Category C.
- The risks were adequately identified by the Principal Investigator and appropriate mitigation was described in the protocol.
- Clarifications were requested.
- A motion was made and seconded to provisionally approve this protocol. The motion was unanimously approved.

**ADMINISTRATIVELY APPROVED ITEMS**:
The KSI database indicates the following items have been given administrative approval since our last meeting:

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| | | | |
|---|---|---|---|
| 24-11-902 | DT | Continuing Review | Active - no changes |
| 22-09-563-1 | DK | Continuing Review | Active - updated personnel only, 3 yr review |
| 22-10-599 | DK | Amendment | Updated personnel only |
| 23-10-736 | DA | Continuing Review | Active - Updated personnel only |
| 23-11-752 | NS | Continuing Review | Active - Updated personnel only - open to enrollment |
| 22-09-565-1 | QL | Continuing Review | Not started - updated personnel only - 3 yr review |
| 22-09-569-1 | QL | Continuing Review | Not started - updated personnel only - 3 yr review |
| 23-01-633-1 | NS | Continuing Review | Active - updated personnel and attachment, 3 yr review |

**OTHER BUSINESS**:
The committee discussed the need to review protocols for FDA authorized products which are Out of Specification (OOS) for commercial release and are used in the FDA's Expanded Access Program (EAP), per NIH Guidelines Section III-C-1. The committee agreed that this use of OOS products does not need IBC approval. This recommendation will be forwarded to Jefferson's Research Compliance group and Legal for approval.

Meeting Adjourned: 10:55 a.m.

Respectfully submitted for the IBC,

/s/Gerald Grunwald, PhD
Chair, Institutional Biosafety Committee

**GG/lc**