MINUTES
INSTITUTIONAL BIOSAFETY COMMITTEE
DATE: September 12, 2025

Attendance: Total Attending: 7 **Voting Members Present**: 6

Called to Order: 10:04 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	
Douglas C. Hooper, PhD	rDNA; Immunology; Gene Transfer	
Botond Igyarto, PhD	Microbiology	X
Loretta Kelly, Esq.	Non-affiliate Community Member	
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	X
Yuri Sykulev, PhD	Microbiology	X

MINUTES REVIEWED:
Minutes of the May 2025, June 2025, and August 2025 meetings were presented for review.

Motion to Approve: Sara Meyer
Seconded: Fabienne Paumet
Total = 6; For-6, Opposed-0, Abstained-0

NEW PROTOCOLS:

1. Principal Investigator M.D.
IBC Control # 25-08-973 "*A Phase 2/3, Open-Label, Randomized, Controlled, Multicenter Study of KYV-101, an Autologous Fully Human Anti-CD19 Chimeric Antigen Receptor T-Cell (CD19 CAR T) Therapy, Versus Ongoing Standard-Of-Care Immunosuppressive Therapy in Patients with Generalized Myasthenia Gravis (KYSA-6)"*

A motion was made and seconded to provisionally approve this protocol. The motion was unanimously approved.

This protocol was reviewed under NIH Category C. The principal risks identified were:
CAR-T cells
Murine Stem Cell Virus
Lentivirus, Replication Incompetent

The risks were adequately identified by the Principal Investigator and appropriate mitigation was described in the protocol.

Protocol Summary:
This research study is intended for people with Myasthenia Gravis that have not responded to earlier standard therapies. The study is testing an experimental treatment called KYV-101, referred to as a chimeric antigen receptor (CAR) T cell therapy. It is a type of therapy made from a person's own immune cells. This therapy may work to kill the cells that can cause the disease.

A genetically modified lentivirus will be used to insert a gene into the participant's T cells to make the KYV-101 CAR-T cells. The new genetic material will tell these T cells to make a new protein that can recognize B cells and kill them. The aim is that the B cells that drive the disease will not recover or will have a long absence.

The product will be manufactured by an outside facility and returned to the treatment facility where the product will be infused into the patient through their vein.

Discussion/Clarifications Requested:

- **Protocol Summary:**
  - Explain what Myasthenia Gravis is.
  - Reduce the details and make the information more succinct.
- **Lay Description:**
  - Explain what Myasthenia Gravis is.

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

Month Day, Year

Protocol #	PI - Initials	Form type	Comments
25-06-958	MM	New	Previously approved
23-08-719	EA	New	Toxin only, previously approved
25-03-936	EA	New	Toxin only, previously approved
22-08-554-1	LG	Continuing Review	Active - no updates, 3 yr renewal
22-01-472-1	LH	Amendment	Updated personnel
23-08-713	KB	Continuing Review	Active - updated personnel only
22-12-614	MT	Amendment	Updated personnel
22-07-523-1	QL	Continuing Review	Active - no updates, 3 yr renewal
21-04-370-1	JM	Amendment	Updated personnel
21-06-395-1	JM	Amendment	Updated personnel
24-05-846	JM	Amendment	Updated personnel
24-07-871	MD	Amendment	Clinical Trial - Updated IB
22-09-560-1	MS	Continuing Review	Active - updated research location only, 3 yr renewal
23-08-714	TP	New	Work with human materials, rDNA, toxin

OTHER BUSINESS:
Ms. Gotta reviewed the changes we are making with our IBC database.

Meeting Adjourned: 11:08 a.m.

Respectfully submitted for the IBC,

/s/Sue Gotta, MS
Institutional Biosafety Officer, Institutional Biosafety Committee

SG/lc