MINUTES
INSTITUTIONAL BIOSAFETY COMMITTEE
DATE: September 11, 2026

Attendance: Total Attending: 11 **Voting Members Present**: 10

Called to Order: 10:01 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
Botond Igyarto, PhD	Microbiology	X
Loretta Kelly, Esq.	Non-Affiliated Community Member	X
Kathleen "Kitty" Kono	Non-Affiliated Community Member	X
Phil LaTourette, DVM	Laboratory Animal Sciences	X
Sara Meyer, PhD	Cancer Biology	
Suzann Ordile	Non-Affiliated Community Member	X
Fabienne Paumet, PhD	Cellular Biology & Biochemistry	X
Holly Ramage, PhD	Immunology & Microbiology	
Michael Root, MD, PhD	Immunology & Microbiology	X
Drake Stierman	Safety Officer	
Megan Watson, MS	Lab Specialist	X

MINUTES REVIEWED:
Minutes of the August 14, 2026 meeting were presented for review.

Motion to Approve: Kitty Kono
Seconded: Phil LaTourette
Total = 10; For-10, Opposed-0, Abstained-0

NEW PROTOCOLS:

1. Principal Investigator U.G. - Philadelphia, PA
IBC Control#26-08-1043 *"A Phase 3 Randomized Controlled Trial of Rondecabtagene Autoleucel, an Autologous, Dual-Targeting CD19/CD20 CAR T-Cell Therapy Product Candidate, Versus Investigator's Choice of CD19 CAR T-Cell Therapy in Patients with Relapsed or Refractory Large B-Cell Lymphoma in the Second-Line Setting (PiNACLE-H2H)"*

Summary:
- The purpose of this study is to evaluate the safety and efficacy of LYL314, a CD19/CD20 dual-targeting CAR-T-cell therapy in patients with aggressive B-Cell Non-Hodgkins Lymphoma.
- This is a human gene transfer study.
- The principal risks identified were:
  - CAR-T cells
  - Lentivirus
- 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. <u>Principal Investigator U.G. - Lehigh Valley Health Network</u>

IBC Control#26-08-1044 *"A Phase 3 Randomized Controlled Trial of Rondecabtagene Autoleucel, an Autologous, Dual-Targeting CD19/CD20 CAR T-Cell Therapy Product Candidate, Versus Investigator's Choice of CD19 CAR T-Cell Therapy in Patients with Relapsed or Refractory Large B-Cell Lymphoma in the Second-Line Setting (PiNACLE-H2H)"*

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- Clarifications were requested.
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<u>ADMINISTRATIVELY APPROVED ITEMS</u>:

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

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Protocol #	PI - Initials	Form type	Comments
24-03-819	A.B.	New	Submittal of previously approved work
25-06-961	A.S.	New	Submittal of previously approved work
25-06-962	A.S.	New	Submittal of previously approved work
21-03-355-1	R.P.	Continuing Review	Active - added human cells & questions related to database update answered
22-06-513	K.V.D.W.	New	Submittal of previously approved work
24-02-790	J.E.	New	Submittal of previously approved work
24-07-874	B.E.	Continuing Review	Active - questions related to database update answered
25-08-971	E.B.	Amendment	Added virus, toxin, and rDNA
22-07-521-1	J.C.	Continuing Review	Active - questions related to database update answered
25-09-982	D.T.	Continuing Review	Active - questions related to database update answered

<u>OTHER BUSINESS</u>:

The committee discussed if clinical trials that are the same, but different locations, need separate protocols. Sue Gotta will contact our Clinical Research staff to confirm.

Meeting Adjourned: 10:43 a.m.

Respectfully submitted for the IBC,

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

GG/lc