

**MINUTES**  
**INSTITUTIONAL BIOSAFETY COMMITTEE**  
**DATE: January 9, 2026**

**Attendance:** 12

**Voting Members Present:** 9

**Called to Order:** 10:01a.m.

<b>Name</b>	<b>Expertise</b>	<b>Present</b>
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	X
Botond Igyarto, PhD	Microbiology	X
Loretta Kelly, Esq.	Non-affiliate Community Member	X
Kathleen “Kitty” Kono	Non-Affiliate Community Member	X
Phil LaTourette, DVM	Laboratory Animal Sciences	X
Sara Meyer, PhD	Cancer Biology	X
Fabienne Paumet, PhD	Cellular Biology & Biochemistry	X
Drake Stierman	Non-Voting Member	X
Megan Watson	Non-Voting Member	X

**MINUTES REVIEWED:**

Minutes of the December 12, 2025 meeting were presented for review.

Motion to Provisionally Approve: Gerald Grunwald

Seconded: Phil LaTourette

Total = 9; For-6, Opposed-0, Abstained-3

The committee discussed the information presented in the Protocol Summary. It was agreed that the minutes would be provisionally approved then reviewed once modified.

**NEW PROTOCOLS:**

**1. Principal Investigator S.N.**

IBC Control #25-12-1000 “*A prospective, multicenter, open-label, randomized, actively controlled, parallel-group Phase 3 clinical trial to evaluate efficacy, safety, and tolerability of IMA203 versus investigator’s choice in patients with previously treated, unresectable or metastatic cutaneous melanoma (ACTengine® IMA203-301)*”

**Summary:**

- This Phase 3 clinical trial aims to treat patients with cutaneous melanoma with IMA203, where their own T cells have been genetically modified to recognize a cancer-specific small protein fragment, PRAME peptide.
- This is a human gene therapy study.
- The principal risks identified were:
  - Engineered 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.

**ADMINISTRATIVELY APPROVED ITEMS:**

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

**January 9, 2026**

Protocol #	PI - Initials	Form type	Comments
22-11-601	PM	Continuing Review	Active - no updates
23-01-635-1	FK	Continuing Review	Active - title and personnel updates, 3 yr review
24-05-855	RS	Amendment	Clinical trial, updated personnel & attached clinical study protocol - added EKGs
23-09-726	AH	Amendment	Clinical trial, updated attachments with recommended Phases 2 dose
23-10-731	JL	Amendment	Added methotrexate, updated Protocol Summary & attached SDS
25-03-934	ZS	Amendment	Added use of cyclophosphamide
24-8-883	FW	Continuing Review	Active - personnel changes only
24-10-892	FW	Continuing Review	Active - no updates
24-11-900	JG	Continuing Review	Active - personnel changes only
22-08-542-1	LM	Continuing Review	Active - personnel changes only, 3 yr review
23-02-654	UMO	Continuing Review	Active - no updates
22-08-534-1	AS	Continuing Review	Active - no updates, 3 yr review
22-01-473-1	SW	Continuing Review	Active - no updates, 3 yr review
22-12-614-1	MT	Continuing Review	Active - personnel changes & updated training record, 3 yr review
23-01-627-1	MT	Continuing Review	Active - personnel changes & deleted toxin, 3 yr review
22-09-568-1	QL	Continuing Review	Not started - no updates, 3 yr review
24-05-848	JM	Continuing Review	Not started - personnel changes only

**OTHER BUSINESS:**

Sue Gotta informed the committee that the commissioning of the 722 BLSB (BL3) and 651 JAH (ABL3) labs is scheduled for the end of this month and is scheduled tentatively for the 352 JAH (ABL3) the end of next month.

Meeting Adjourned: 10:27 a.m.

Respectfully submitted for the IBC,

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

**GG/lc**