MINUTES
INSTITUTIONAL BIOSAFETY COMMITTEE
DATE: November 14, 2025

Attendance: Total Attending: #11 **Voting Members Present**: # 9

Called to Order: 10:02 a.m.

Name	Expertise	Present
Linda Cassidy, MS	Non-Voting Member	
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
Yuri Sykulev, PhD	Microbiology	

GUESTS INTRODUCED: Environmental Health and Safety Department staff members DS and MW were introduced to the committee. Both of these individuals will become members of the committee as they take on more of the responsibilities of the BSO as she plans for retirement.

MINUTES REVIEWED:
Minutes of the September 12, 2025, meeting were presented for review.

Motion to Approve: Botond Igyarto
Seconded: Sara Meyer
Total = 9; For-7, Opposed-0, Abstained-2

NEW PROTOCOLS:

1. Principal Investigator HI
IBC Control #25-10-984 "*A Phase 1, Multicenter Open-label, Dose-Finding Study to Investigate the Safety and Pharmodynamics of a Singel Intrathecal injection of INS1202 in Patients with Amyotrophic Lateral Sclerosis"*

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 risk identified was:
Adenoviral vector AAV9

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

Protocol Summary:
This clinical trial is intended for people with Amyotrophic Lateral Sclerosis (ALS). Mutations in the SOD1 gene are thought to produce a toxic gain-of-function by causing the protein to misfold and aggregate within motor neurons. INS1202 is an engineered self-complementary adeno-associated virus serotype 9 (scAAV9) vector that encapsulates a short hairpin ribonucleic acid (shRNA) against SOD1. The expression of the shRNA is designed to suppress the endogenous human SOD1 mRNA, leading to decreased levels of the protein, and thus leading to less of the misfolded and aggregate in ALS patients, thus slowing disease progression.

Discussion/Clarifications Requested:
- **Protocol Summary:**
  - Need a better description of the experimental approach and endpoints
  - Clarify that the vector is produced off-site
- **Lay Summary**
  - Also needs a better description of the endpoints
  - Final paragraph is a repeat of the last two sentences of the paragraph above and can be deleted
- **Biological Agent**
  - Biosafety level for AAV9 needs to be changed to BL2
- **Security, Shipping, Transport, and Training**
  - Confirm BBP training

2. Principal Investigator BB
IBC Control #25-10-983 "*A Phase 1, Non-Randomized, Open-Label, Single-Center, Dose Escalation Trial of Heterologous Prime-Boost Vaccination with Ad5.F35-hGUCY2C-PADRE and Lm-GUCY2C Vaccines in Adults with Colon Cancer at High Risk or Relapse after Definitive Surgical and Adjuvant Therapy"*

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

This protocol was reviewed under NIH Category C. The principal risk identified was:
Adenovirus
Listeria monocytogenes

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

Protocol Summary:
This clinical trial is intended for people with colon cancer who are at a high risk for relapse after definitive surgical removal and adjuvant therapy. Experiments in mice showed that a prime/boost regimen using Ad5.F35-hGUCY2C-PADRE followed by Lm-GUCY2C elicited the strongest immune response and antitumor activity. The goal of the trial is to see if there is a similar effect in patients with the goal of training their immune systems to recognize and kill cancer cells.

Discussion/Clarifications Requested:
Other than some minor spelling issues, the protocol was well written.

3. Principal Investigator RS
IBC Control #25-10-985 "*A Phase 1/2 study evaluating genetically modified autologous T cells expressing a T-cell receptor recognizing a cancer/germline antigen as monotherapy or in combination with nivolumab in patients with recurrent and/or refractory solid tumors (AC Tengine® IMA203-101)"*

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 risk identified was:
Human T-cells
Lentiviral vector

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

Protocol Summary:
This clinical trial is to study the use of IMA203 either alone or in combination with nivolumab in patients with recurrent or refractory solid tumors. IMA203 is engineered via a third-generation lentiviral vector to produce a PRAME specific $CD8^+$ T-cell product. PRAME (Preferentially Expressed Antigen in Melanoma) is found on cancer cells but not on most normal cells. Patients who carry the genetic type HLA-A*02:01 and whose tumor expresses PRAME, will undergo leukapheresis. The product is shipped to an offsite lab where the modifications to their T cells will occur. The product is then shipped back to be transfused into the patient. All patients will receive chemotherapy prior to the transfusion to help the new cells work better, and some patients will receive nivolumab along with the transfusion.

Discussion/Clarifications Requested:
- **Lay Summary**
  - A few technical terms, such as leukapheresis, need to be defined
  - Add some of the information from the safety section for completeness' sake

4. Principal Investigator MK
IBC Control #25-11-987 "*Intermediate-size Population Expanded Access Program (EAP) for Ciltacabtagene autoleucel (cita-cel) Out of Specification (OOS) in patients with Multiple Myeloma."*

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 risk identified was:
Human T-cells
Lentiviral vector

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

Protocol Summary:
Ciltacabtagene autoleucel (cita-cel) is already in clinical trial. It is a CAR-T cell therapy using BCMA (B-cell maturation antigen). This clinical trial is for the purpose of using a patient's cita-cel product even when it does not meet the release criteria, which makes it not FDA approved for use in patients. The reason for the product being out of specification is that the patients' T-cells by this point are not very good and/or are not of sufficient quantity for the manufacturing process. However, another leukapheresis procedure either isn't possible or isn't likely to yield a better starting product. Given the fact that these patients don't have further options available, an EAP protocol represents a final chance at stabilizing their disease.

Discussion/Clarifications Requested:
- **Biological Agents**
  - CAR-T cells can replicate while the lentiviral vector used to manufacture them is replication incompetent
- **Recombinant or Synthetic Nucleic Acid Molecules**
  - In this case, the source of the nanobodies to build the CAR is llama.

ADMINISTRATIVELY APPROVED ITEMS:

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

November 14, 2025

Protocol #	PI - Initials	Form type	Comments
23-10-735	DA	Continuing Review	Active - updated personnel only
22-10-585	SM	Amendment	Added 5-Fluorouracil, updated protocol summary, added SDS
25-03-934	ZS	Amendment	Added mouse breast cancer cell line
22-07-533-1	UG	Continuing Review	Active - Clinical Trial, closed to enrollment, 3yr renewal
23-09-726	AH	Continuing Review	Active - Clinical Trial, open to enrollment, updated personnel
21-08-424	UG	Continuing Review	Active - Clinical Trial, closed to enrollment
24-10-893	MS	Continuing Review	Closed to enrollment, 1 active patient, updated personnel, research location & attached Protocol Clarification Letter
24-05-855	RS	Amendment	Updated attached IB, Clinical trial
25-10-986	BW	NEW	Toxin - calcitrol
24-10-898	PS	Continuing Review	Active-no updates-open to enrollment-clinical trial
23-01-623	LI	Continuing Review	Active-no updates
24-11-901	MT	Continuing Review	Active-updated personnel
25-02-932	MK	Amendment	Updated PI to LVHN
24-10-894	FW	Continuing Review	Active-no updates
24-08-882	BB	Continuing Review	Active-no updates-open to enrollment-clinical trial
23-10-729	UG	Continuing Review	Active-no updates-open to enrollment-clinical trial
25-09-982	DT	NEW	Work with CAR-T cells recognizing UPAR

October 10, 2025

Protocol #	PI - Initials	Form type	Comments
23-10-730	JC	Continuing Review	Active - no updates
22-07-527-1	HY	Continuing Review	Active - updated personnel/biological agents question, 3yr review
25-09-981	YH	New	Previously approved - added codon-anticodon pairing/tRNA
23-03-665	MS	Continuing Review	Active - no updates
23-10-731	JL	Amendment	Added retroviral vectors
21-08-424	UG	Amendment	Updated attached clinical protocol and IB
24-10-898	PS	Amendment	Updated attached clinical protocol
24-09-886	MO	Continuing Review	Open to enrollment, updated personnel, attached IB and protocol
24-07-871	MD	Amendment	SUSAR event updated attachments
21-07-403-1	FP	Amendment	Updated research location
23-04-672	FP	Amendment	Updated research location
23-08-710	JS	Continuing Review	Active - updated personnel only
23-09-723	QL	Continuing Review	Not started - plan to start in near future

OTHER BUSINESS:

Ms. Gotta mentioned the exhaust fan issues in BLSB. Two of the exhaust fans are not working currently. Chemical fume hoods are pulling air, just at a lower volume. They can still be used safely, but any concerns are to be relayed to EH&S for evaluation. Parts are on order to repair the issue and should be in shortly.

Ms. Gotta updated the committee on the BL3 and ABL3 construction projects.

Ms. Gotta also confirmed with the committee that she can review and approve the bacteria used in one of the teaching labs on CC.

Dr. Grunwald has reached out to Dr. Novelli regarding new members for this committee.

Meeting Adjourned: 10:55a.m.

Respectfully submitted for the IBC,

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

GG/sg