

**INSTITUTIONAL BIOSAFETY COMMITTEE (IBC)
MEETING MINUTES - DUARTE**

Monday, 07/21/2025

VOTING MEMBERS PRESENT: Marcin Kortylewski, Scientist, Chair
Srividya Swaminathan, Scientist, Vice-Chair
Tamara Casebolt, Biosafety Officer
Richard Ermel, Veterinarian
Rowelle Enriquez, Laboratory Protections Director
Rebecca Lally, Community Member
Vinod Pullarkat, Scientist/Physician
Brenda Aguilar, Scientist/Lab Personnel (Alternate for Renate Starr)

VOTING MEMBERS ABSENT: Renate Starr, Scientist/Lab Personnel

NON-VOTING MEMBERS PRESENT: Ashraf Amshaqn, Biosafety Specialist (Alternate for Tamara Casebolt)

STAFF PRESENT: Charlene Dekalb, Jennifer Kim, Linna Makmura
GUEST PRESENT: Ariana Ortega

1. CALL TO ORDER

The meeting was conducted remotely. The chair called the meeting to order at 4:00 PM.

a. Confidentiality Notice

Attendees were reminded that information brought before the committee are confidential and may only be used for committee business.

b. Conflict of Interest Declaration

Attendees were reminded that they declare if there is a known conflict of interest with any submissions being discussed. Conflicts of interest include:

1. Where an immediate family member of the member is involved in the design, conduct, and reporting of the research.
2. Where the member holds a financial interest related to the research being reviewed.
3. When the member is named on the protocol.
4. Any other situation where the member believes that another interest conflicts with his/her ability to deliberate objectively on a protocol.

c. Public Posting

Public meeting notice was posted with no comments/questions from the public received.

2. OLD BUSINESS

a. Review of Minutes

The minutes of the meeting held on 06/16/2025 were reviewed. No issues were raised, and a motion was made to approve the minutes as written. The approved minutes will be posted for public access at www.cityofhope.org.

DECISION: The Minutes of the Meeting Held on 06/16/2025 Approved

Voting: Total=8, For=8, Against=0, Abstain=0

b. **Deferred**

No deferred business discussed.

3. **NEW BUSINESS**

a. **Safety Office Report**

Please see the report attached to the agenda in iRIS.

b. **IBC Membership Update**

The Committee announced Dr. Saro Armenian as the new Institutional Official.

c. **Review of Policies and Guidelines**

No New Policies

d. **Initial Review**

IBC 25027 (III-C)	Ref # 288051	BSL2
AMC-112: Axicabtagene Ciloleucel in Relapsed or Refractory HIV-Associated Aggressive B-cell Non-Hodgkin Lymphoma		
PI: Baird, John, M.D.		
This Phase I study investigates the safety and preliminary efficacy of CAR T-cell therapy in people living with well-controlled HIV who have relapsed/refractory B-cell non-Hodgkin lymphoma (B-NHL), particularly diffuse large B-cell lymphoma (DLBCL). The trial aims to address the exclusion of this population from prior CAR-T studies and expand access to potentially life-saving treatment.		
The assigned IBC Primary Reviewer presented the Primary Review. The training of personnel and proposed work/containment level for listed facilities were reviewed and verified. The committee went through the comments made by the pre-reviewers. No other issues were raised during the discussion.		
DECISION: Protocol Approved with Comment(s) That Must Be Addressed		
Total Members Voting: 8		
[For: 8 Absent: 0 Against: 0 Conflict of Interest: 0 Not Present: 0 Abstained: 0]		
COMMENTS THAT MUST BE ADDRESSED:		
<ul style="list-style-type: none"> • Additional details requested for recombinant materials. • Update signage to current locations and procedures for clinical preparation and administration 		

IBC 25033 (III-D)	Ref # 288846	BSL2
Process development for adoptive immunotherapy		
PI: Lin, Chih-Min (Stephen), Ph.D.		
The CBM project focuses on optimizing manufacturing strategies for CAR-modified immune cells used in cancer immunotherapy. It evaluates closed, automated systems for cell production		

while maintaining product quality, and identifies the most feasible process based on key parameters like cell proliferation, transduction efficiency, phenotype, and functional assays. The goal is to ensure consistent, GMP-compliant production of high-quality CAR-T cells.

The assigned IBC Primary Reviewer presented the Primary Review. The training of personnel and proposed work/containment level for listed facilities were reviewed and verified. The committee went through the comments made by the pre-reviewers. No other issues were raised during the discussion.

DECISION: Protocol Modification(s) Required to Secure Approval

Total Members Voting: **8**

[For: **8** Absent: **0** Against: **0** Conflict of Interest: **0** Not Present: **0** Abstained: **0**]

COMMENTS THAT MUST BE ADDRESSED:

- Additional clarification requested regarding experimental procedures.
- Clarify if there is work with human cell lines and source of all tumor cell lines.
- Additional details requested for recombinant materials.
- Additional details requested for non-recombinant materials.
- Updates requested for chemical and drug inventory.
- Clarification on locations and containment levels for specific experiments and research requested.
- Update decontamination and waste disposal procedure to Institutional Safety standards.

e. Third-Year Renewal(s)

IBC 22045 (III-D)	Ref # 287947	BSL2/ABSL2
The Sweet Tooth as a Sensitive Assay for Dissection & Treatment of Citrin Deficiency		
PI: Brenner, Charles, Ph.D.		
This study investigates how citrin deficiency affects sweet and alcohol aversion through liver hormone expression in vivo under reductive stress. Researchers will test two therapeutics—a NADH oxidase and a gold nanoparticle—to see if they alleviate symptoms by restoring NAD+ levels.		
The assigned IBC Primary Reviewer presented the Primary Review. The training of personnel and proposed work/containment level for listed facilities were reviewed and verified. The committee went through the comments made by the pre-reviewers. No other issues were raised during the discussion.		
DECISION: Protocol Approved		
Total Members Voting: 8		
[For: 8 Absent: 0 Against: 0 Conflict of Interest: 0 Not Present: 0 Abstained: 0]		
<ul style="list-style-type: none"> • The PI and Personnel have been appropriately trained. • Any concerns were promptly addressed / protocol complied with IBC standards. • The listed facilities have been inspected and are appropriate for the proposed 		

work/containment level.

IBC 16022 (III-D)	Ref # 288559	BSL2
DOSE PREPARATION OF TRANSDUCED NEURAL PROGENITOR CELLS		
PI: Lin, Chih-Min (Stephen), Ph.D.		
This project involves the clinical-grade production of human neuronal progenitor cells which were transduced with a lentiviral vector encoding. The cells were manufactured under cGMP conditions, tested for safety (including RCL negativity), and prepared for clinical dosing.		
The assigned IBC Primary Reviewer presented the Primary Review. The training of personnel and proposed work/containment level for listed facilities were reviewed and verified. The committee went through the comments made by the pre-reviewers. No other issues were raised during the discussion.		
DECISION: Protocol Approved		
Total Members Voting: 8		
[For: 8 Absent: 0 Against: 0 Conflict of Interest: 0 Not Present: 0 Abstained: 0]		
<ul style="list-style-type: none">• The PI and Personnel have been appropriately trained.• Any concerns were promptly addressed / protocol complied with IBC standards.• The listed facilities have been inspected and are appropriate for the proposed work/containment level.		

IBC 01005 (III-D)	Ref # 288163	BSL2/ABSL2
Role of epigenetic factors and noncoding RNAs in the pathogenesis of diabetes and its complications		
PI: Natarajan, Rama, Ph.D.		
This project explores how diabetes-related factors like high glucose, unhealthy lipids, and growth factors, cause long-term damage to the kidneys, blood vessels, and heart. Using cell cultures and in vivo models of Type 1 and Type 2 diabetes, researchers will study how these factors alter protein and non-coding RNA expression and trigger epigenetic changes. The goal is to identify therapeutic strategies that can prevent or reverse tissue injury and improve diabetes management.		
The assigned IBC Primary Reviewer presented the Primary Review. The training of personnel and proposed work/containment level for listed facilities were reviewed and verified. The committee went through the comments made by the pre-reviewers. No other issues were raised during the discussion.		
DECISION: Protocol Approved with Comment(s) That Must Be Addressed		
Total Members Voting: 8		
[For: 8 Absent: 0 Against: 0 Conflict of Interest: 0 Not Present: 0 Abstained: 0]		
COMMENTS THAT MUST BE ADDRESSED:		

- Additional clarification requested regarding In Vivo work.
- Clarify collaborator providing non-recombinant biological materials.
- Updates requested for chemical and drug inventory.
- Updated information requested for personnel.

IBC 10021 (III-D)	Ref # 288248	BSL2/ABSL2
SUMOYLATION INHIBITORS		
PI: Rosen, Steven, M.D., FACP, FASCO		
<p>This project evaluates the anti-cancer potential of SUMOylation inhibitors in various preclinical models, including in vivo bearing human colorectal, breast, pancreatic, and lymphoma tumors. Researchers will test these inhibitors alone or in combination with radiation, DNA damage response inhibitors, and CAR-T cell therapy to assess their ability to enhance anti-tumor effects and immune responses. Additional studies will explore their therapeutic potential in dexamethasone-resistant multiple myeloma and investigate mechanisms of resistance.</p>		
<p>The assigned IBC Primary Reviewer presented the Primary Review. The training of personnel and proposed work/containment level for listed facilities were reviewed and verified. The committee went through the comments made by the pre-reviewers. No other issues were raised during the discussion.</p> <p>DECISION: Protocol Approved Total Members Voting: 8 [For: 8 Absent: 0 Against: 0 Conflict of Interest: 0 Not Present: 0 Abstained: 0]</p>		
<ul style="list-style-type: none"> • The PI and Personnel have been appropriately trained. • Any concerns were promptly addressed / protocol complied with IBC standards. • The listed facilities have been inspected and are appropriate for the proposed work/containment level. 		

IBC 19001 (III-D)	Ref # 287879	BSL2+/ABSL1+
Immunobiology of normal and malignant lymphopoiesis		
PI: Swaminathan, Srividya, Ph.D.		
<p>This study investigates how specific oncogenes drive B and T cell lymphoid malignancies and alter immune responses. Using in vivo models, immune cell knockouts, and humanized xenografts, the research aims to uncover how oncogenes shape tumor-immune interactions and identify immune subsets that can be targeted for non-toxic, precision immunotherapies. The ultimate goal is to develop therapies that selectively eliminate malignant lymphocytes while preserving healthy tissue.</p>		
<p>The assigned IBC Primary Reviewer presented the Primary Review. The training of personnel and proposed work/containment level for listed facilities were reviewed and verified. The committee went through the comments made by the pre-reviewers. No other issues were raised during the discussion.</p>		

DECISION: Protocol Approved

Total Members Voting: **8**

[For: **7** Absent: **0** Against: **0** Conflict of Interest: **1** Not Present: **0** Abstained: **0**]

- The PI and Personnel have been appropriately trained.
- Any concerns were promptly addressed / protocol complied with IBC standards.
- The listed facilities have been inspected and are appropriate for the proposed work/containment level.

IBC 94017 (III-D)

Ref # 288853

BSL2/ABSL2

TRANSGENIC/KNOCKOUT ANIMAL PRODUCTION "BLANKET PROTOCOL"

PI: Tsark, Walter, Ph.D.

This Core Facility at City of Hope specializes in generating genetically modified in vivo models to support the research needs of institutional investigators. These models are essential tools for studying gene function and disease mechanisms in vivo.

The assigned IBC Primary Reviewer presented the Primary Review. The training of personnel and proposed work/containment level for listed facilities were reviewed and verified. The committee went through the comments made by the pre-reviewers. No other issues were raised during the discussion.

DECISION: Protocol Approved with Comment(s) That Must Be Addressed

Total Members Voting: **8**

[For: **8** Absent: **0** Against: **0** Conflict of Interest: **0** Not Present: **0** Abstained: **0**]

COMMENTS THAT MUST BE ADDRESSED:

- Update funding sources if applicable
- Updates requested for chemical and drug inventory.
- Verify no changes to personnel.

f. **Amendment(s)**

No submissions reviewed.

g. **Other**

No submissions reviewed.

4. ADJOURNMENT

List of Protocols not meeting the criteria for full committee review (not discussed in the meeting) was displayed in the meeting.

There being no further business, the meeting was adjourned at 4:50 PM.

