INSTITUTIONAL BIOSAFETY COMMITTEE (IBC) MEETING MINUTES - DUARTE

Monday, 06/16/2025

VOTING MEMBERS PRESENT: Marcin Kortylewski, Scientist, Chair

Srividya Swaminathan, Scientist, Vice-Chair

Tamara Casebolt, Biosafety Officer

Rowelle Enriquez, Laboratory Protections Director

Renate Starr, Scientist/Lab Personnel Stephen R. Hodgson, Community Member Rebecca Lally, Community Member

Mike Chen, Physician

ALTERNATE MEMBERS Ashraf Amshagn, Biosafety Specialist (Alternate for Tamara

PRESENT: Casebolt)

James Finlay, Veterinarian (Alternate for Richard Ermel)

STAFF PRESENT: Charlene Dekalb, Jennifer Kim

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 must 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.

a. OLD BUSINESS

a. Review of Minutes

The minutes of the meeting held on 05/19/2025 were reviewed. No issues were raised, and a motion was made to approve the minutes as written.

DECISION: The Minutes of the Meeting Held on 05/19/2025 Approved

Voting: Total=9, For=6, Against=0, Abstain=3

b. IBC 24040 (III-D) Ref # 274619 (BSL2/ABSL2)

Study previously reviewed with comments that must be addressed. Response to comments were requested to be reviewed by the Full Committee. The training of personnel and proposed work/containment level for listed facilities were reviewed and verified.

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

Total Members Voting: 9

[For: 8 Absent: 0 Against: 0 Conflict of Interest: 0 Not Present: 1 Abstained: 0]

3. NEW BUSINESS

a. Safety Office Report

Please see the report attached to the agenda in iRIS.

Discussion of NIH Reportable Event – Accidental needlestick injury while injecting HeLa cells into mice. All safety training was up to date at the time of the incident.

b. **IBC Membership Update**

Not applicable

c. Review of Policies and Guidelines

POLICY – IBC Guideline: IBC Minutes Public Posting

DECISION: Approved (06/16/2025)

d. Initial Review

IBC 25024 (III-D)	Ref # 287142	BSL2/ABSL2
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Role of epigenetic regulators in hematopoiesis and leukemogenesis

PI: Qian, Zhijian, Ph.D.

This study uses replication-incompetent retroviruses and lentiviruses to deliver genes that play a role in epigenetic regulator into cell lines and primary cells to investigate their roles in leukemia. Gene expression is validated using standard laboratory protein quantification technique, while functional effects on cell viability and molecular mechanisms are assessed both in vitro and in vivo using mouse leukemia models. Therapeutic responses to protein chimeras and small molecule inhibitors are evaluated in xenograft models using immunodeficient mice.

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: 9

[For: 9 Absent: 0 Against: 0 Conflict of Interest: 0 Not Present: 0 Abstained: 0]

COMMENTS THAT MUST BE ADDRESSED:

- Additional clarification requested regarding experimental procedures.
- Additional clarification requested regarding In Vivo work.
- Additional details requested for recombinant materials.
- Specify BSL2+ containment for work with lentivirus containing oncogenic inserts in protocol.
- Specify IRB protocol associated with Human Source cell lines in protocol.
- Update decontamination and waste disposal procedure to Institutional Safety standards.
- Updates requested for chemical and drug inventory.
- Locations need to be updated, and an initial walk-through/inspection scheduled with Biosafety.
- Updated information requested for personnel.

e. Third-Year Renewal(s)

IBC 19009 (III-D)	Ref # 287592	BSL2/ABSL2

Cytolmmune: Mouse tumor models for Immunotherapy

PI: Caligiuri, Michael A., M.D.

This study evaluates the efficacy and safety of modified immune cells as cellular therapy—and bispecific antibody fusion proteins in treating solid tumors and blood cancers, including breast cancer brain metastasis, multiple myeloma, and leukemia. Tumor models are established using various tumor cell lines in mice, and immune cells are engineered using replication defective retrovirus and attenuated oncolytic herpes simplex virus vectors. The modified cells are designed to enhance tumor cell killing through targeted cytotoxicity, supporting the development of novel cancer immunotherapies.

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: 9

[For: 9 Absent: 0 Against: 0 Conflict of Interest: 0 Not Present: 0 Abstained: 0]

COMMENTS THAT MUST BE ADDRESSED:

- Additional clarification requested regarding the purpose of experimental procedures.
- Updated information requested for personnel.
- Additional clarification requested regarding In Vivo work.
- Include the numbers for IRB protocols covering human source materials.
- Clarification on locations for specific experiments and research requested.
- Updated information requested for personnel.
- Update decontamination and waste disposal procedure to Institutional Safety standards.

IBC 16011 (III-D)	Ref # 287532	BSL2

EXPANSION AND CARDIOMYOCYTE DIFFERENTIATION OF HIPSCS

PI: Chen, Chang-yi (Vincent), Ph.D.

The team is adapting an established method for producing cardiomyocytes from human embryonic stem cells (hESC-CMs) to human induced pluripotent stem cells (hiPSCs). These hiPSC-derived cardiomyocytes (hiPSC-CMs) will be supplied to collaborators for use in laboratory and animal studies. The goal is to support research into heart disease and regenerative therapies using scalable cell production techniques.

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: 9

For: 9 Absent: 0 Against: 0 Conflict of Interest: 0 Not Present: 0 Abstained: 0

COMMENTS THAT MUST BE ADDRESSED:

- Cite any relevant publications/presentations that are indicative of progress with this study.
- Additional clarification requested regarding the purpose of experimental procedures.
- · Personnel must fulfill additional training requirements.

IBC 13011 (III-D)	Ref # 287112	BSL2+

BIOPHYSICAL INVESTIGATION OF PROTEINS

PI: Talisman, Tijana, Ph.D.

This study uses super-resolution microscopy and other biophysical techniques to investigate protein-protein, protein-ligand, and protein-lipid interactions in commercial cell lines, as well as in primary cells and extracellular vesicles. Replication-defective Lentiviral vectors carrying reporter genes are used to knock down specific opiod receptors and validate antibody-based imaging. Recombinant DNA is used for transfection and protein production, with a focus on developing new high-resolution imaging and quantification methods for extracellular vesicles and immune synapses.

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: 9

[For: 9 Absent: 0 Against: 0 Conflict of Interest: 0 Not Present: 0 Abstained: 0]

COMMENTS THAT MUST BE ADDRESSED:

Personnel must fulfill additional training requirements.

f. Amendment(s)

IBC 17028 (III-D)	Ref # 284104	BSL2+/ABSL1+	
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GENETIC AND EPIGENETIC STUDIES IN CANCERS

PI: Chen, Jianjun, Ph.D.

This research investigates genetic and epigenetic mechanisms—particularly protein coding and non-coding RNA—in cancers such as AML, lymphoma, and glioblastoma (GBM), using both coding and non-coding RNAs. An engineered oncolytic HSV-1 vector is used for targeted virotherapy in GBM, with modifications to enhance tumor specificity and reduce toxicity. The study combines in vitro and in vivo models to explore how epigenetic changes influence tumor susceptibility, therapeutic response, and resistance, with additional focus on microRNA-based therapies and nanoparticle delivery systems.

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: 9

For: 9 Absent: 0 Against: 0 Conflict of Interest: 0 Not Present: 0 Abstained: 0]

COMMENTS THAT MUST BE ADDRESSED:

- Additional clarification requested regarding experimental procedures.
- Additional clarification requested regarding In Vivo work.
- Final SOP for HSV-1 vector must be approved by Biosafety.

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 5:20 PM.