# Draft Minutes of the CWRU Institutional Biosafety Committee

IBC of record for the Louis Stokes Cleveland VAMC

## Meeting Date: August 14, 2025

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**Members Present:**

Charles Bark, Ronald Conlon, John Durfee, Craig Hodges (Chair), Kenneth Maytreyek, Monica Montano (Vice Chair), Reshmi Parameswaran, Alexander Rodriguez-Palacios, Ivy Samuels (VA rep), Aaron Severson, Pamela Vanderzalm, Andrew Young

**Ex-Officio Members and Guests:**

Colleen Karlo

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**Meeting Convened: 3:02 PM via Zoom**

The Chair reminded all members that any conflicts of interest related to a submission must be declared prior to the start of the discussion. Members with a conflict will be temporarily moved to the virtual waiting room for the duration of the relevant discussion.

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**Approval of Minutes**

The IBC Chair asked members for discussion or additional changes to the draft minutes. There were minor changes recommended.

Motion: Approval of the July meeting minutes with the additional, specific changes.
For: 10 | Absent: 2 | Against: 0 | Conflict of Interest: 0 | Abstained: 0

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**Safety and Incident Reporting** - None

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**Review of Prior Business**

Training and facility issues that were identified at the July meeting have been addressed.

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Charles Bark and John Durfee join the meeting.

**Review of New Protocols:**

Investigator: Agata Exner
Project Title: Ultrasound-mediated targeted nucleic acid delivery using gas-core lipid nanoparticles
IBC Protocol: #IBC-2025-557

Project Overview, Risk Assessment and Discussion:
The research involves the use of human and murine cancer cell lines expressing reporter genes in animal models. The lab will generate lipid nanoparticles carrying nucleic acid cargo (mRNA, siRNA, cDNA) for delivery to the models that received the cancer cell lines. The committee recommended revisions for clarity regarding the flow of the procedural steps. Work practices, procedures, and facilities are consistent with BSL2 containment for handling of human cells, and safe sharps practices and PPE are described. The animals receiving the recombinant/synthetic nucleic acids can be housed in a standard housing room following administration.

NIH Guidelines: III-D-4

Training and Facilities: The Investigator and laboratory staff have completed basic lab safety and biosafety training. There were no concerns regarding the facilities to accommodate the safety and containment requirements of the proposed experiments.

Vote: Approve at BSL2 with minor edits.
For: 12 | Absent: 0 | Against: 0 | Conflict of Interest: 0 | Abstained: 0

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Investigator: Divita Mathur
Project Title: Dosing DNA nanoparticles in human cells
IBC Protocol: #IBC-2025-558

Project Overview, Risk Assessment and Discussion:
The researchers generate and use synthetic DNA nanoparticles which serve as both the delivery carrier and the functional payload (reporter genes and gene editing components). After synthesis of the nanoparticles, they will be introduced into human cell lines in culture. Work practices, procedures, and facilities are consistent with BSL2 containment for work with human cells and appropriate for the planned research, but minor edits are needed for the description of their handling of waste and use of the biosafety cabinet.

NIH Guidelines: III-E

Training and Facilities: The Investigator and laboratory staff have completed basic lab safety and biosafety training. There were no concerns regarding the facilities to accommodate the safety and containment requirements of the proposed experiments.

Vote: Approve at BSL2 with minor edits.
For: 12 | Absent: 0 | Against: 0 | Conflict of Interest: 0 | Abstained: 0

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Kenneth Matreyek moved to the waiting room due to a conflict.

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Investigator: Kenneth Matreyek
Project Title: LentEvolver: A lentiviral vector platform for protein directed evolution in mammalian cells
IBC Protocol: #IBC-2025-555

Project Overview, Risk Assessment and Discussion:
The committee has requested additional information in order to conduct an adequate risk assessment of the proposed research.

Vote: Table
For: 11 | Absent: 0 | Against: 0 | Conflict of Interest: 1 | Abstained: 0

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Investigator: Kenneth Matreyek
Project Title: Genomic integration of protein-coding sequences into mammalian landing pad cell lines
IBC Protocol: #IBC-2025-556

Project Overview, Risk Assessment and Discussion:
The investigator will use promoterless cDNAs transfected into human engineered cell lines to study expression of proteins ranging from those involved in infectious disease to rare developmental disorders. No toxins or oncogenes will be investigated. The cell lines contain a cassette that enables integration of the plasmid to a specific location that contains an inducible promoter, selectable marker, and reporter genes. Work practices, procedures, and facilities are consistent with BSL2 containment and appropriate for the planned research. Minor edits are needed, including the description of handling of liquid waste.

NIH Guidelines: III-E

Training and Facilities: The Investigator and laboratory staff have completed basic lab safety and biosafety training. There were no concerns regarding the facilities to accommodate the safety and containment requirements of the proposed experiments.

Vote: Approve at BSL2 with minor edits.
For: 11 | Absent: 0 | Against: 0 | Conflict of Interest: 1 | Abstained: 0

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Kenneth Matreyek rejoins the meeting.

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**Review of Continuing Protocols:**

Investigator: Alex Gifford
Project Title: An Open-label, Phase 1/2 Trial of Gene Therapy 4D-710 in Adults with Cystic Fibrosis
IBC Protocol: #IBC-2021-437

Project Overview, Risk Assessment and Discussion:
The study uses a recombinant AAV vector expressing human CFTR gene for aerosol administration to cystic fibrosis patients. Work practices, procedures, and facilities are consistent with BSL1 containment and include respiratory protection for personnel present during administration, and appropriate for the planned research.

NIH Guidelines: III-C

Training and Facilities: The Investigator and co-investigators have completed training on the NIH Guidelines and bloodborne pathogens. There were no concerns regarding the facilities to accommodate the safety and containment requirements of the proposed experiments.

Vote: Approve at BSL1 with respiratory protection during administration.
For: 12 | Absent: 0 | Against: 0 | Conflict of Interest: 0 | Abstained: 0

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Investigator: Zheng-Rong Lu
Project Title: Multifunctional delivery systems for siRNA
IBC Protocol: #20090703

Project Overview, Risk Assessment and Discussion:
Replication incompetent lentiviral vectors will be used to deliver reporter genes to human and murine cancer cell lines, which will later be introduced into animal models. The lab will assemble lipid nanoparticles with siRNA

and miRNA for delivery to animal models. Work practices, procedures, and facilities are consistent with BSL2 containment and appropriate for the planned research; standard housing is appropriate for animals carrying recombinant or synthetic nucleic acids. Administrative updates and minor updates of waste handling procedures are needed.

NIH Guidelines: III-D-1, III-D-4

Training and Facilities: The Investigator and laboratory staff have completed basic lab safety and biosafety training. There were no concerns regarding the facilities to accommodate the safety and containment requirements of the proposed experiments.

Vote: Approve at BSL2 with minor edits.
For: 12 | Absent: 0 | Against: 0 | Conflict of Interest: 0 | Abstained: 0

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Investigator: Amit Mahipal
Project Title: A Phase 1b Study to Evaluate the Safety, Tolerability and Preliminary Efficacy of ATP150/ATP152, VSV-GP154 and Ezabenlimab (BI 754091) in Patients with KRAS G12D/G12V Mutated Pancreatic Ductal Adenocarcinoma
IBC Protocol: #IBC-2023-484

Project Overview, Risk Assessment and Discussion:
The study involves the use of protein vaccines and a viral vector for treatment of pancreatic cancer. Work practices and procedures for preparation and administration are consistent with BSL2 containment.

NIH Guidelines: III-C

Training and Facilities: The Investigator and co-investigators have completed training on the NIH Guidelines and bloodborne pathogens. There were no concerns regarding the facilities to accommodate the safety and containment requirements of the proposed experiments.

Vote: Approve at BSL2
For: 12 | Absent: 0 | Against: 0 | Conflict of Interest: 0 | Abstained: 0

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**Amendments:**

Investigator: Yuan Gao
Project Title: Function and Target of ETV6 in Ewing Sarcoma

IBC Protocol: #IBC-2024-524

Project Overview, Risk Assessment and Discussion:
The protocol involves the use of replication incompetent lentiviruses for delivery of genes for overexpression or gene editing components in mammalian cancer cells. The amendment adds additional cancer cells to be used in the approved experimental procedures. Work practices and procedures are consistent with BSL2 containment and appropriate for the planned research, and animals can be housed in a standard housing room following the administration of cells.

NIH Guidelines:III-D-1, III-D-3, III-D-4, III-E

Training and Facilities: The Investigator and laboratory staff have completed basic lab safety and biosafety training. There were no concerns regarding the facilities to accommodate the safety and containment requirements of the proposed experiments

Vote: Approve at BSL2
For: 12 | Absent: 0 | Against: 0 | Conflict of Interest: 0 | Abstained: 0

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Investigator: Xin Qi
Project Title: Regulation of mitochondrial activity in Alzheimer's disease
IBC Protocol: #IBC-2020-365

Project Overview, Risk Assessment and Discussion:
The protocol involves the use of a recombinant AAV for expression of genes in animal models and the amendment adds new transgenes. No toxins or oncogenes will be expressed. Work practices and procedures are consistent with BSL1 containment and appropriate for the planned research.

NIH Guidelines: III-D-4, III-E

Training and Facilities: One individual needs biosafety retraining. There were no concerns regarding the facilities to accommodate the safety and containment requirements of the proposed experiments.

Vote: Approve at BSL2
For: 12 | Absent: 0 | Against: 0 | Conflict of Interest: 0 | Abstained: 0

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Investigator: Dominique Durand

Project Title: Bioelectric activity and the implications in cancer growth and metastasis
IBC Protocol: #IBC- 2021-429

Project Overview, Risk Assessment and Discussion:
The protocol has been approved for the use of murine cell lines containing recombinant nucleic acids in animal models. The amendment adds a new cell line but does not alter the risk assessment. Work practices and procedures are consistent with BSL1 containment and appropriate for the planned research.

NIH Guidelines: III-D-4

Training and Facilities: The Investigator and laboratory staff have completed basic lab safety and biosafety training. There were no concerns regarding the facilities to accommodate the safety and containment requirements of the proposed experiments.

Vote: Approve at BSL1
For: 12 | Absent: 0 | Against: 0 | Conflict of Interest: 0 | Abstained: 0

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Investigator: Rachel Mann
Project Title: Case Transgenic and Targeting Facility Core Protocol
IBC Protocol: #IBC-20080404

The Core received 3 orders for the generation of transgenic mice.

Vote: Approve at BSL1
For: 12 | Absent: 0| Against: 0 | Conflict of Interest: 0 | Abstained: 0

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**Notice of Administrative Amendments**

| IBC # | PI | Title | Amendment |
|---|---|---|---|
| 2023-480 | Gifford | Phase 1/2 Dose-escalation Study Evaluating the Safety, Tolerability, and Efficacy of VX-522 in Subjects 18 Years of Age and Older With Cystic Fibrosis and a CFTR Genotype Not Responsive to CFTR Modulator Therapy | Updated sponsor document with no change to IBC protocol or risk assessment |

**Notice of Terminated Protocols**

| IBC # | PI | Title |
|---|---|---|
| 2023-470 | Lee | Inflammation in the brain due to SARS-COV-2 Infection in mouse |

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**Other Business**

The committee reviewed data provided from Dr. Stephanie Langel regarding environmental sampling of animal cages following administration of a recombinant viral vaccine. The committee did not recommend any changes to the biosafety measures or procedures currently in place.

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**Next Meeting**: September 11, 2025

**Meeting Adjourned**: 3:58 PM.