



Minutes of the CWRU Institutional Biosafety Committee

IBC of record for the Louis Stokes Cleveland VAMC

Meeting Date: September 11, 2025

Members Present:

Charles Bark, Scott Becka (VA rep), Cheryl Cameron, Ronald Conlon, John Durfee, Craig Hodges (Chair), Kenneth Maytrejek, Monica Montano (Vice Chair), Sophia Onwuzulike, Reshmi Parameswaran, Alexander Rodriguez-Palacios, Aaron Severson, John Tilton, Koen van Besien, Pamela Vanderzalm, Andrew Young

Ex-Officio Members and Guests:

Colleen Karlo

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.

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 August meeting minutes with the additional, specific changes.

For: 16 | Absent: 0 | Against: 0 | Conflict of Interest: 0 | Abstained: 0

Safety and Incident Reporting - None

Review of Amendment:

Investigator: Mitchell Drumm

Project Title: Testing platforms for strategies to treat genetic diseases

IBC Protocol: #IBC-2021-415



Project Overview, Risk Assessment and Discussion:

The amendment to the protocol is adding the use of virus-like particles for delivery of a protein base editor and gRNA in animal models. The particles do not contain any viral genetic material. Work practices, procedures, and facilities are consistent with BSL2 and appropriate for the planned research, with animals housed in a standard housing room.

NIH Guidelines: III-D-4

Training and Facilities: A few lab personnel are due to retrain, and they will be notified to complete training. There were no concerns regarding the facilities to accommodate the safety and containment requirements of the proposed experiments.

Vote: Approve at BSL2

For: 16 | Absent: 0 | Against: 0 | Conflict of Interest: 0 | Abstained: 0

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

Review of Prior Business

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 reviewed a revised protocol with more details regarding the design of the cell culture experiments and the safety features of the replication incompetent lentiviral vector, including pseudotyping and an inducible promoter to significantly mitigate the risk of vector transduction and transgene expression resulting from an exposure. The viral vector will be used in cell culture with human cell lines and the planned experiments involve marker and reporter genes as transgenes. Work practices, procedures, and facilities are consistent with BSL2 containment and appropriate for the planned research.

NIH Guidelines III-D-1, III-D-3

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: 15 | Absent: 0 | Against: 0 | Conflict of Interest: 1 | Abstained: 0

John Tilton leaves the meeting.

Review of New Protocols:

Investigator: Kenneth Matreyek

Project Title: Pseudotyped lentiviral vectors for cell engineering and biological research

IBC Protocol: #IBC-2025-559

Project Overview, Risk Assessment and Discussion:

The research will involve replication incompetent lentiviral vectors for overexpression of genes of interest in human and murine cell lines in culture. The viruses will be pseudotyped with different glycoproteins and express fluorescent and luminescent reporter genes. Work practices, procedures, and facilities are consistent with BSL2 containment and appropriate for the planned research.

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

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: 14 | Absent: 1 | Against: 0 | Conflict of Interest: 1 | Abstained: 0

Kenneth Matreyek returns to the meeting.

Investigator: Wenjian Gan

Project Title: Elucidating Novel PRMT Regulatory Mechanisms and Their Roles in Tumorigenesis

IBC Protocol: #IBC-2025-560

Project Overview, Risk Assessment and Discussion:

Replication incompetent lentiviral vectors will be used to overexpress, knockout, or knockdown human genes involved in human cancer cell lines in culture. The committee suggested that risks could further be reduced by

IBC Meeting Minutes, September 11, 2025



separating the gRNA and nuclease on separate viral vectors and the researchers should consider this approach. Some of the modified cell lines will be introduced into animal models. Work practices, procedures, and facilities are consistent with BSL2 containment, and safe sharps practices and PPE are described.

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

Training and Facilities: The Investigator and laboratory staff have completed basic lab safety and biosafety training. Inspection of the facilities noted that the signage for the room needs to be updated, and the biosafety cabinet needs to be certified.

Vote: Approve at BSL2 with minor edits.

For: 15 | Absent: 1 | Against: 0 | Conflict of Interest: 0 | Abstained: 0

Ron Conlin is moved to the waiting room for a conflict of interest.

Review of Continuing Protocols:

Investigator: Rachel Mann

Project Title: Case Transgenic and Targeting Facility Core Protocol

IBC Protocol: #20080404

Project Overview, Risk Assessment and Discussion:

The protocol is for the generation of transgenic or genetically modified mice using recombinant DNA, mRNA, or AAV vectors. Each animal order is reviewed to assess risk, with a process for additional committee review if containment of ABSL2 work was anticipated. The amendment includes a change in PI. Work practices, procedures, and facilities are consistent with BSL1 containment and appropriate for the planned research.

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 BSL1

For: 14 | Absent: 1 | Against: 0 | Conflict of Interest: 1 | Abstained: 0

Ron Conlon rejoins the meeting. Reshmi Parameswaran is moved into the waiting room for a conflict of interest.



Investigator: Reshmi Parameswaran

Project Title: Regulation of Natural Killer cell function by NF- κ B.

IBC Protocol: #IBC-2016-244

Project Overview, Risk Assessment and Discussion:

The protocol uses replication incompetent lentiviral vectors for gene modulation in human immune cells in cell culture and for expression of reporter genes in human cancer cell lines. The modified cells will be introduced into animal models, which will be housed in a standard housing room. Work practices, procedures, and facilities are consistent with BSL2 containment, and safe sharps practices and PPE are described.

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

Training and Facilities: A few lab members need to be due for retraining. There were no concerns regarding the facilities to accommodate the safety and containment requirements of the proposed experiments.

Vote: Approve at BSL2 upon completion of training

For: 14 | Absent: 1 | Against: 0 | Conflict of Interest: 1 | Abstained: 0

Reshmi Parameswaran rejoins the meeting.

Investigator: Boaz Tirosh

Project Title: Regulation of gene expression during stress in tumors

IBC Protocol: #IBC-2022-460

Project Overview, Risk Assessment and Discussion:

The research will use replication incompetent lentiviral vectors and adenoviruses for human and rodent gene expression and gene modulation in human and murine cells in culture. Some of these modified cells will be introduced into mice which will be housed in a standard housing room. Work practices, procedures, and facilities are consistent with BSL2 containment, and safe sharps practices and PPE are described. Non-K12 strains of E. coli will be used to generate recombinant proteins under BSL1 conditions.

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

Training and Facilities: Some personnel are due for retraining. There were no concerns regarding the facilities to accommodate the safety and containment requirements of the proposed experiments.

IBC Meeting Minutes, September 11, 2025



Vote: Approve at BSL2 with minor edits.

For: 15 | Absent: 1 | Against: 0 | Conflict of Interest: 0 | Abstained: 0

Reshmi Parameswaran is moved into the waiting room for a conflict of interest.

Investigator: Parameswaran Ramakrishnan

Project Title: Regulation of NF-kB activation in autoimmunity and inflammation

VA Title: Targeting Hexosamine Biosynthetic Pathway and OGlcnAcylation to Treat AML

IBC Protocol: #IBC-2013-158

Project Overview, Risk Assessment and Discussion:

The research will use replication incompetent lentiviral and retroviral vectors for gene modulation in human and murine cells in culture, including expression of shRNA and CRISPR/Cas9 systems. Non-viral experiments include the introduction of siRNA into cells in culture. Some genetically modified cells will be introduced into animal models, which will be housed in a standard housing room. Work practices, procedures, and facilities are consistent with BSL2 containment, and safe sharps practices and PPE are described.

NIH Guidelines III-D-1, III-D-3, III-D-4, III-F

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: 14 | Absent: 1 | Against: 0 | Conflict of Interest: 1 | Abstained: 0

Reshmi Parameswaran returns to the meeting. Koen van Besien (conflict) and Scott Becka leave the meeting.

Amendments:

Investigator: Koen van Besien

Project Title: A phase 1 single arm, open label study to evaluate the safety of UF-KURE-BCMA cells in patients with relapsed or refractory Multiple Myeloma

IBC Protocol: #IBC-2024-527

Project Overview, Risk Assessment and Discussion:

There were minor changes to clinical trial protocol which do not change the risk assessment of the research. The amendment changes the PI on the study and the committee had no concerns; the new PI has completed required training. Work practices, procedures, and facilities are consistent with BSL2 containment and appropriate for the planned research.

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

Vote: Approve at BSL2

For: 12 | Absent: 3 | Against: 0 | Conflict of Interest: 1 | Abstained: 0

Notice of Administrative Amendments

IBC #	PI	Title	Amendment
2020-383	Bonomo	Bonomo Studies	Updates to personnel, funding, research location

Notice of Terminated Protocols

IBC #	PI	Title
2021-425	Gerken	Role of GalNAc-Ts in MCF-7 Cell Line Model of Breast Cancer
2013-161	Shatat	Therapeutic relevance of c-myc inhibition by a small molecule activator of protein phosphatase 2A in murine models of myc-dependenct cancer
2019-345	Matreyek	Multiplex Mutational Analyses of Viral Neutralization Mechanisms Against Human Restriction Factors

Other Business

The committee reviewed a draft IBC Charter document to replace the current *Procedures for Use of Recombinant or Synthetic Nucleic Acid Molecules* document. A few suggestions were made, and these will be incorporated and the revised document sent to the Institutional Official for approval.

Next Meeting: October 9, 2025

Meeting Adjourned: 4:05 PM.