Minutes of the CWRU Institutional Biosafety Committee

IBC of record for the Louis Stokes Cleveland VAMC

Meeting Date: 09/10/2026

Members Present:

Charles Bark, Cheryl Cameron, Ronald Conlon, Suhrim Fisher (Veterinarian), Craig Hodges (Chair), Kenneth Maytreyek, Monica Montano (Vice Chair), Reshmi Parameswaran, Ivy Samuels (VA rep), John Tilton, Aaron Severson, Pamela Vanderzalm, Andrew Young

Ex-Officio Members and Guests:

Colleen Karlo, Lorrie Rice

Meeting Convened: 3:00 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: 11 | Absent: 2 | Against: 0 | Conflict of Interest: 0 | Abstained: 0

Safety and Incident Reporting - None

Dr. Matreyek joins the meeting.

Review of Prior Business – The committee discussed IBC submissions with pending approvals that are contingent on completion of training. The IBC Chair may send an email reminder to the PI, emphasizing PI responsibilities and the requirement for IBC approval to conduct the research.

Review of New Protocols:

Investigator: Mohamed Hammad
Project Title: Genetic Editing of CAR T and NK Cells
IBC Protocol: #IBC-2026-574

Project Overview, Risk Assessment and Discussion:
This study utilizes replication-incompetent lentiviral vectors to express reporter proteins in tumor cells in cell culture. These modified cells will be introduced into animal models. Lipid nanoparticles will be used as a delivery system for mRNA in animal models. Animals will be housed at ABSL2 for 7 days following administration. Room location edits are needed in the study application. Work practices, procedures, and facilities are consistent with BSL2 standards, and safe sharps practices and PPE are described.

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

Training and Facilities: One individual is past due for lab safety 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 and completion of training.
For: 12 | Absent: 1| Against: 0 | Conflict of Interest: 0 | Abstained: 0

Dr. Cameron joins the meeting.

Investigator: Issa John
Project Title: Interrogation of neural circuits during complex behaviors
IBC Protocol: #IBC-2026-591

Project Overview, Risk Assessment and Discussion:
This protocol utilizes replication incompetent AAV and EnvA-pseudotyped, glyocoprotein-deleted rabies virus delivered to animal models in sequence. The animals will be housed at ABSL2 following rabies administration. Work practices, procedures, and facilities are consistent with BSL2 standards, and safe sharps practices and PPE are described.

NIH Guidelines: III-D-1, 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 with minor edits
For: 13 | Absent: 0 | Against: 0 | Conflict of Interest: 0 | Abstained: 0

Review of Continuing Protocols:

Investigator: Abhinav Acharya
Project Title: Development of CAR-macrophages for treatment of cancer
IBC Protocol: #IBC-2023-493

Project Overview, Risk Assessment and Discussion:
This study involves modifying macrophages using DNA plasmids to express an antigen receptor and fluorescent marker. Cancer cells expressing a reporter gene will be introduced into animal models, followed by the introduction of modified macrophages. Animals will be housed in a standard housing room. Work practices, procedures, and facilities are consistent with BSL2 standards and appropriate for the planned research.

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

Training and Facilities: There is training needed for two individuals. Inspection of the facilities noted that the biosafety cabinet needs to be certified.

Vote: Approve at BSL2 upon completion of training and a plan to certify the BSC.
For: 13 | Absent: 0 | Against: 0 | Conflict of Interest: 0 | Abstained: 0

Investigator: David Buchner
Project Title: Regulation of adipocyte differentiation and function and PPARg signaling
IBC Protocol: #IBC-2017-281

Project Overview, Risk Assessment and Discussion:
The research involves generating recombinant lentiviral vectors to deliver shRNA (for gene knockdown) and cDNA (for gene expression) for targeting and overexpressing human and murine genes. The lentivirus is replication incompetent using a 4-plasmid vector system. Work practices, procedures, and facilities are consistent with BSL2 standards 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: 13 | Absent: 0 | Against: 0 | Conflict of Interest: 0 | Abstained: 0

Investigator: Leah Gates
Project Title: The role of metabolism in regulating chromatin and gene expression
IBC Protocol: #IBC-2023-498

Project Overview, Risk Assessment and Discussion:
The laboratory uses replication-incompetent lentiviral vectors to deliver CRISPR/Cas9 gene-editing constructs murine intestinal organoids, and to overexpress genes of interest in human colon cancer cell lines. Recombinant E. coli (BL21 strain) is used to produce and purify proteins for biochemical studies. Work practices, procedures, and facilities are consistent with BSL2 standards and appropriate for the planned research.

NIH Guidelines: III-D-1, III-D-3, 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: 13 | Absent: 0 | Against: 0 | Conflict of Interest: 0 | Abstained: 0

Investigator: Richard Premont
Project Title: Nitric oxide as a novel regulator of alternative splicing
IBC Protocol: #IBC-2023-497

Project Overview, Risk Assessment and Discussion:
This research uses plasmid-based and lentiviral vectors to introduce recombinant and synthetic nucleic acid molecules into human cell lines. The study involves expressing, knocking down, or editing human genes. The work also includes using E. coli bacteria to produce specified recombinant proteins for analysis. Work practices, procedures, and facilities are consistent with BSL2 standards and appropriate for the planned research.

NIH Guidelines: III-D-1, III-D-3, 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: 13 | Absent: 0| Against: 0 | Conflict of Interest: 0 | Abstained: 0

Investigator: Rodrigo Somoza
Project Title: MSCs as probes: Non-destructive evaluation of cellular differentiation during in vitro chondrogenesis
IBC Protocol: #IBC-2014-201

Project Overview, Risk Assessment and Discussion:
This project involves the use of replication incompetent lentiviral vector system to deliver recombinant DNA into cultured human cells. The recombinant materials consist of plasmids containing human genes linked to fluorescent or luminescent reporter genes. Researchers will generate lentiviral particles to infect human cell cultures, including stem cells, cartilage cells, and muscle cells, allowing them to track cellular development. Work practices, procedures, and facilities are consistent with BSL2 standards 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: 13 | Absent: 0| Against: 0 | Conflict of Interest: 0 | Abstained: 0

Investigator: Xiongwei Zhu
Project Title: Mitochondrial dysfunction in neurodegenerative diseases
IBC Protocol: #IBC-2017-271

Project Overview, Risk Assessment and Discussion:
This research utilizes replication incompetent AAV and lentiviral vectors to modulate gene expression in human and murine cell cultures. AAV may be introduced into animal models, which can be housed in a standard housing room following injection. Work practices, procedures, and facilities are consistent with BSL2 standards and appropriate for the planned research.

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

Training and Facilities: One individual needs to complete biosafety retraining. 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: 13 | Absent: 0 | Against: 0 | Conflict of Interest: 0 | Abstained: 0

Dr. Hodges moves to the waiting room, and Dr. Montano takes over as chair.

Amendments:

Investigator: Craig Hodges
Project Title: Cystic Fibrosis correction through gene editing
IBC Protocol: #IBC-2019-346

Project Overview, Risk Assessment and Discussion:
The amendment adds a new gene variant for investigation and new routes of delivery to animal models. The risks associated with the generation of aerosols have been adequately addressed using engineering controls. Work practices, procedures, and facilities are consistent with BSL2 standards and appropriate for the planned research.

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

Vote: Approve at BSL2
For: 12 | Absent: 0 | Against: 0 | Conflict of Interest: 1 | Abstained: 0

Dr. Hodges joins the meeting and resumes as chair. Dr. Parameswaran leaves the meeting.

Investigator: Leland Metheny

Project Title: Phase 1 Study of BAFF CAR-T cells (LMY-920) for Treatment of Relapsed or Refractory Myeloma
IBC Protocol: #IBC-2022-458

Project Overview, Risk Assessment and Discussion:
The amendment requests a change in PI and provides updated study documents. The changes to the study protocol do not impact the risk assessment, and the new PI has provided an attestation of PI responsibilities. There were no concerns regarding the proposed experiments.

NIH Guidelines: III-C

Vote: Approve at BSL2
For: 12 | Absent: 0 | Against: 0 | Conflict of Interest: 1 | Abstained: 0

Notice of Administrative Amendments

IBC #	PI	Title	Amendment
IBC-2025-554	Scavuzzo	Viral-mediated knockouts in Enteric Glial Cells	Personnel
IBC-2023-488	Yu	Overcoming Inhibitory collagens to Promote Recovery after Acute versus Chronic Spinal Cord Injury	Personnel
IBC-2024-532	Yu	Development and function of the sensory circuits - BSL2	Personnel
IBC-2024-535	Yu	Development and function of the sensory circuits - BSL1	Personnel
IBC-2021-435	Yoshida	Determine the molecular mechanisms of therapy resistance to advance current melanoma therapy.	Personnel
IBC-2026-589	Scavuzzo	Modulating Glial States in-vivo using viral gene expression tools	Personnel
IBC-20080905	Tesar	Reprogramming of cells with virally expressed genes	Personnel
IBC-2025-548	Clayton	Modulating glial cell state in vivo using viral gene expression and modulation	Personnel
IBC-2025-549	Clayton	Modulating glial cell state in vitro using viral gene expression and modulation	Personnel

Notice of Terminated Protocols

IBC #	PI	Title
IBC-2017-279	Schmaier	Lung Metastasis of Transfected Breast Cancer Cells
IBC-2013-155	Lee	Imaging Hepatocellular Carcinoma (HCC)
IBC-2024-511	Yendewa	IPCAVD014/HTX1004A Safety, Immunogenicity and Efficacy Phase 1/2a Study of a Heterologous Ad26.Mos4.HIV, MVA-BN-HIV Vaccine Regimen Plus Broadly Neutralizing Antibodies PGT121, PGDM1400 and VRC07-523LS in HIV-1 Infected Adults on Suppressive ART.

Other Business –
IBC Meeting Minutes, September 10, 2026

C. Karlo presented an overview of new biosafety policies: USG Policy for Stopping High-Risk Life Sciences Research and the NIH draft Biosafety Policy.

Next Meeting: 10/15/2026

Meeting Adjourned: 4:04 PM.