Minutes of the CWRU Institutional Biosafety Committee

IBC of record for the Louis Stokes Cleveland VAMC

Meeting Date: October 15, 2026

Members Present:

Cheryl Cameron, Ronald Conlon, Suhrim Fisher (Veterinarian), Craig Hodges (Chair), Kenneth Maytreyek, Monica Montano (Vice Chair), Sophia Onwuzulike, Reshmi Parameswaran, Ivy Samuels (VA rep), Aaron Severson, Pamela Vanderzalm, Marissa Wolfe (alternate Veterinarian*), Andrew Young

Ex-Officio Members and Guests:

Colleen Karlo, Lorrie Rice, Brian O'Connell (VA)

* ***Abstained from voting since primary veterinarian were present.***

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

Safety and Incident Reporting - None

Dr. Vanderzalm arrives.

Review of Continuing Protocols:

Investigator: Robert Bonomo **VA Research**
Project Title: Bonomo Studies
IBC Protocol: IBC-2020-383

Project Overview, Risk Assessment and Discussion:
This research involves expressing genes from various bacteria, including Acinetobacter, Pseudomonas, and Mycobacterium, within laboratory strains of Escherichia coli using plasmid vectors. The work is conducted exclusively in cell culture to produce and purify these proteins or for susceptibility testing. Work practices, procedures, and facilities are consistent with BSL2 standards and appropriate for the planned research.

NIH Guidelines: III-D-2

Training and Facilities: One individual needs to complete 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: 11 | Absent: 1 | Against: 0 | Conflict of Interest: 0 | Abstained: 0

Dr. Samuels leaves, Dr. Cameron arrives.

Review of New Protocols:

Investigator: Marilia Cascalho
Project Title: Determining B cell responses in health and disease and utilizing CAR T-cell immunotherapy against cancer
IBC Protocol: IBC-2026-593

Project Overview, Risk Assessment and Discussion:
This study involves the use of genetically modified bacteria and mammalian immune cells. Researchers will construct and introduce recombinant strains of Citrobacter rodentium and Salmonella enterica subsp. into animal models, which will be housed at ABSL2. Murine tumor cells expressing a reporter gene will also be used in animal models. Additionally, replication-incompetent retroviral vectors will be produced and introduced into primary mouse T cells to express a chimeric antigen receptor (CAR). These modified T cells will be introduced into animal models. Work practices, procedures, and facilities are consistent with BSL2 standards, and safe sharps practices and PPE are described. The disinfectants used in the animal facility need to be added.

NIH Guidelines: III-D-1, III-D-2, III-D-3, III-D-4

Training and Facilities: The Investigator and one laboratory staff member needs to complete basic lab safety/ 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 and completion of training
For: 11 | Absent: 1 | Against: 0 | Conflict of Interest: 0 | Abstained: 0

Investigator: Ty Miller
Project Title: Synthetic Chimeric Antigen Receptor Targeting Brain Tumor Markers
IBC Protocol: IBC-2026-592

Project Overview, Risk Assessment and Discussion:
This study utilizes replication-incompetent, viral-vector-based lentiviruses to introduce recombinant/synthetic nucleic acids into cultured human immune cells, including T cells, natural killer cells, and macrophages, as well as tumor organoid models. 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: 11 | Absent: 1 | Against: 0 | Conflict of Interest: 0 | Abstained: 0

Investigator: Andrew Pieper
Project Title: Determine if pharmacologically restoring and maintaining impaired NAD+/NADH homeostasis will prevent pathology in preclinical models of alpha-synuclein-driven Parkinson' s Disease (PD).
IBC Protocol: IBC-2026-596

Project Overview, Risk Assessment and Discussion:
This research project uses a 3rd generation lentiviral vector system to deliver genetic material into human

induced pluripotent stem cells (iPSCs) to induce differentiation into neurons. Work practices, procedures, and facilities are consistent with BSL2 standards and appropriate for the planned research.

NIH Guidelines: III-D-1

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

Investigator: John Tilton
Project Title: Lentivirus production - CFAR core service
IBC Protocol: IBC-2026-598

Project Overview, Risk Assessment and Discussion:
The facility uses recombinant DNA to produce lentiviral vectors and Human Immunodeficiency Virus (HIV-1) within a laboratory setting. They utilize packaging cell lines, which are transfected with plasmids containing genes from HIV and other viruses to generate viral particles. These particles are intended for use as a core service for other researchers and include a verification step that researchers obtaining viruses from the core will have an IBC protocol in place. 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 with minor edits
For: 11 | Absent: 1 | Against: 0 | Conflict of Interest: 0 | Abstained: 0

Review of Continuing Protocols (continued):

Investigator: Kaixiang Cao
Project Title: Deciphering the roles of epigenetic modifiers in stem cell maintenance and differentiation

IBC Protocol: IBC-2023-499

Project Overview, Risk Assessment and Discussion:
The proposed research involves plasmid cloning in bacteria and the use of replication-incompetent lentiviral vectors to perform gene knockdown, gene overexpression, and CRISPR/Cas9-mediated gene editing in cell culture. The committee is requiring additional safety precautions clearly described (sealed centrifuge rotors and cups, HEPA filter on vacuum line, double gloves) and recommends pseudotyping with an ecotropic envelope protein. 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 with specific edits
For: 11 | Absent: 1 | Against: 0 | Conflict of Interest: 0 | Abstained: 0

Investigator: Rodrigo Somoza
Project Title: Mesenchymal Stem Cell and cancer cell interactions in the extravasation process in metastasis.
IBC Protocol: IBC-2014-200

Project Overview, Risk Assessment and Discussion:
This research uses a third-generation, replication-incompetent lentiviral vector to modify human cells. The experiments involve silencing specific human genes using shRNA and expressing reporter proteins to track the cells' behavior. Modified human mesenchymal stem cells and cancer cell lines are first grown in culture and then introduced into animals, which are housed in a standard housing room. A minor edit regarding the disinfectant used in the animal facility is needed. 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

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

Amendments:

Investigator: Johannes von Lintig
Project Title: Functional analysis of proteins involved in vitamin A and carotenoid metabolism
IBC Protocol: 20110902

Project Overview, Risk Assessment and Discussion:
This amendment adds the use of a replication incompetent lentiviral vector system in cell culture. 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: One lab member is due for re-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: 11 | Absent: 1 | Against: 0 | Conflict of Interest: 0 | Abstained: 0

Investigator: Akihiro Yoshida
Project Title: Melanoma Therapy Resistance and Signaling Manipulation
IBC Protocol: IBC-2021-435

Project Overview, Risk Assessment and Discussion:
The amendment adds a funding source and expands the cancer cell lines to be investigated in cell culture. Replication incompetent lentiviral vectors will investigate new human genes and the expression of reporter genes. Some of 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 standards, and safe sharps practices and PPE are described.

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

Training and Facilities: 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: 1| Against: 0 | Conflict of Interest: 0 | Abstained: 0

Review of Continuing Protocols (continued):

Investigator: Derek Taylor
Project Title: Recombinant Expression and Purification of Human Telomere and Telomerase Proteins
IBC Protocol: IBC-2023-502

Project Overview, Risk Assessment and Discussion:
This research project utilizes recombinant DNA plasmids containing human genes to direct gene expression in target host cells. The experimental procedures involve non-pathogenic Escherichia coli bacteria for plasmid propagation as well as recombinant baculovirus vectors for gene transfer into insect cells in cell culture. Work practices, procedures, and facilities are consistent with BSL2 standards and appropriate for the planned research.

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

Training and Facilities: One individual needs to complete retraining; the Investigator and other laboratory staff are current with 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 and completion of training
For: 11 | Absent: 1 | Against: 0 | Conflict of Interest: 0 | Abstained: 0

Dr. Cameron and Dr. Severson leave.

Amendments (continued):

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 amendment adds experiments using CAR-T cells in a new cancer model in animals. The animals for this experiment will be housed in a standard housing room. Work practices, procedures, and facilities are appropriate for the planned research.

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

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

Vote: Approve at BSL2
For: 9 | Absent: 3 | Against: 0 | Conflict of Interest: 0 | Abstained: 0

Investigator: David Wald
Project Title: Cellular Therapy Testing in Cancer Model
IBC Protocol: IBC-2021-405

Project Overview, Risk Assessment and Discussion:
The amendment adds personnel and updates experiments that will be performed at CWRU and the updated research locations. The committee oversight will be the introduction of cultured cells containing recombinant DNA into animal models, which will be housed in a standard housing room. Work practices and procedures are consistent with BSL2 standards and appropriate for the planned research.

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

Training and Facilities: The individual being added needs to complete 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 upon completion of training
For: 9 | Absent: 3 | Against: 0 | Conflict of Interest: 0 | Abstained: 0

Dr. Conlon leaves.

Investigator: Ron Conlon
Project Title: Case Transgenic and Targeting Facility Core Protocol
IBC Protocol: #IBC-20080404

Project Overview, Risk Assessment and Discussion:
The committee reviewed the generation of new mouse models.

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: 8 | Absent: 3| Against: 0 | Conflict of Interest: 1 | Abstained: 0

Notice of Terminated Protocols

IBC #	PI	Title
IBC-2023-503	Flask	Mouse Cancer Models for Magnetic Resonance Fingerprinting Development
IBC-2023-507	Manor	Lentivirus IBC

Other Business -
The committee discussed the criteria for when a submission approval should be held for verification of BSC certification. If a BSC is more than 3 months past due for certification, the IBC approval will be contingent upon the documented certification. If less than 3 months past due, the PI needs to document the plan and estimated timing for certification for approval.

Next Meeting: November 12, 2026

Meeting Adjourned: 3:57 PM.