



Draft Minutes of the CWRU Institutional Biosafety Committee

IBC of record for the Louis Stokes Cleveland VAMC

Meeting Date: August 13, 2026

Members Present:

Charles Bark, Scott Becka (alternate VA rep), Ronald Conlon, Suhrim Fisher (Veterinarian), Craig Hodges (Chair), Kenneth Maytreyek, Monica Montano (Vice Chair), Sophia Onwuzulike, Reshmi Parameswaran, Aaron Severson, Koen van Besien, Pamela Vanderzalm, Andrew Young

Ex-Officio Members and Guests:

Colleen Karlo

Meeting Convened: 3:01 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 July meeting minutes with the additional, specific changes.

For: 9 | Absent: 4 | Against: 0 | Conflict of Interest: 0 | Abstained: 0

Safety and Incident Reporting - none

Review of Prior Business

NIH Office of Science Policy (OSP) accepted the submitted incident reports. The request for approval for Dr. Dacks toxin experiment was approved by NIH OSP at BSL1.



Review of New Protocols:

Investigator: Berkley Gryder

Project Title: Mechanisms of Androgen Receptor Inverse Agonists in Advanced Prostate Cancer

IBC Protocol: IBC-2026-582

Project Overview, Risk Assessment and Discussion:

This study utilizes replication-incompetent lentiviral vectors to transfer recombinant and synthetic nucleic acids into cultured human cells. Viral particles are generated using a multi-plasmid packaging system before being introduced into various human cancer cell lines. 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: Two individuals need training, 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 with minor edits and completion of training.

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

Dr. van Besien arrives.

Investigator: Marissa Scavuzzo

Project Title: Modulating Glial States in-vivo using viral gene expression tools

IBC Protocol: IBC-2026-589

Project Overview, Risk Assessment and Discussion:

This study utilizes recombinant replication-incompetent lentiviral vectors to introduce reporter genes into mammalian cancer cell lines. The transduced cancer cells are subsequently introduced into animal models, which will be housed in a standard housing room following administration. 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: Two individuals need to complete lab safety retraining and will be notified. There were no concerns regarding the facilities to accommodate the safety and containment requirements of the proposed experiments.

IBC Meeting Minutes, August 13, 2026



Vote: Approve at BSL2 upon completion of training

For: 13 | Absent: 0 | Against: 0 | Conflict of Interest: 0 | Abstained: 0

Investigator: Jacob Witten

Project Title: Optimization of nucleic acid delivery

IBC Protocol: IBC-2026-590

Project Overview, Risk Assessment and Discussion:

This study evaluates lipid nanoparticles and engineered delivery systems containing synthetic and recombinant nucleic acid molecules. Researchers utilize non-pathogenic E. coli bacteria for plasmid constructs, generate nanoparticles/delivery vehicles, and investigate the delivery of cargo in human cells in culture and animal models. [REDACTED].

Work practices, procedures, and facilities are appropriate for the planned research. Experiments that fall under III-E and III-F are described using BSL1 containment, all other work will follow BSL2 containment.

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

Training and Facilities: The Investigator and laboratory staff have completed basic lab safety and biosafety training. NIH Guidelines training is needed for a few individuals. There were no concerns regarding the facilities to accommodate the safety and containment requirements of the proposed experiments.

Vote: Approve at BSL2 with minor changes and completion of training.

For: 13 | Absent: 0 | Against: 0 | Conflict of Interest: 0 | Abstained: 0

Review of Continuing Protocols:

Investigator: Hung-Ying Kao

Project Title: Targeting Promyelocytic Leukemia Protein (PML) in Breast Cancer

IBC Protocol: IBC-2020-375

Project Overview, Risk Assessment and Discussion:

This study utilizes plasmids and recombinant lentiviral vectors to overexpress (cDNA) or knockdown (shRNA) genes of interest in human breast cancer cells in cell culture. Modified human cancer cells are subsequently introduced into an animal model and 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-3, III-D-4

IBC Meeting Minutes, August 13, 2026



Training and Facilities: Some lab members need training, and they will be notified to complete training. Inspection of the facilities noted that the biosafety cabinet needs to be certified.

Vote: Approve at BSL2

For: 13 | Absent: 0 | Against: 0 | Conflict of Interest: 0 | Abstained: 0

Dr. van Besien leaves the meeting.

Investigator: Leland Metheny

Project Title: Phase II Trial of O6-benzylguanine (BG) and Temozolomide (TMZ) therapy of glioblastoma multiforme (GBM) with infusion of autologous P140KMGMT + hematopoietic progenitors to protect hematopoiesis

IBC Protocol: IBC-2021-395

Project Overview, Risk Assessment and Discussion:

The clinical study involves autologous hematopoietic stem cells transduced with a replication incompetent lentiviral vector to express a gene that protects cells from the toxic effects of chemotherapy. The manufacturing of the cells will be done locally, and the cell product administered to research participants that pass the release testing. Work practices, procedures, and facilities are consistent with BSL2 containment and appropriate for the planned research.

NIH Guidelines: III-C

Training and Facilities: The Investigator co-investigators have completed required 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: 1 | Abstained: 0

Dr. Montano leaves the meeting.

Investigator: Tsan Xiao

Project Title: Mechanisms of innate immune signaling

IBC Protocol: IBC-2023-486

IBC Meeting Minutes, August 13, 2026



Project Overview, Risk Assessment and Discussion:

This research project utilizes replication-incompetent retroviral and lentiviral vectors, synthetic guide RNA with Cas9 protein, and small interfering RNA to alter gene expression in cell culture. Escherichia coli bacteria is used for protein production. Work practices, procedures, and facilities are consistent with BSL2 standards and appropriate for the planned research.

NIH Guidelines: 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: 11 | Absent: 2 | Against: 0 | Conflict of Interest: 0 | Abstained: 0

Dr. Montano returns to the meeting.

Investigator: Zhenghe Wang

Project Title: Targeting PIK3CA mutant cancers

IBC Protocol: IBC-2020-382

Project Overview, Risk Assessment and Discussion:

This research involves cell culture and animal models using human and mouse cancer cell lines containing recombinant nucleic acid molecules. The engineered cell lines are cultured in vitro and subsequently introduced into animal models and animals 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-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

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



Sophia Onwuzulike leaves the meeting.

Investigator: Sichun Yang

Project Title: Assessing the efficacy of a repurposed drug in mouse models of drug-resistant breast cancer

IBC Protocol: IBC-2020-360

Project Overview, Risk Assessment and Discussion:

Human cancer cell lines will be genetically modified in cell culture using plasmids containing luciferase reporter genes. Following cell culture manipulations, the modified human cells will be introduced into animal models and the animals housed in a standard housing room. Work practices, procedures, and facilities are consistent with BSL2 standards and appropriate for the planned research with human cell lines.

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: 11 | Absent: 2 | Against: 0 | Conflict of Interest: 0 | Abstained: 0

Investigator: Ron Yu

Project Title: Overcoming Inhibitory collagens to Promote Recovery after Acute versus Chronic Spinal Cord Injury

IBC Protocol: IBC-2023-488

Project Overview, Risk Assessment and Discussion:

This study utilizes replication-incompetent adeno-associated viral (AAV) vectors expressing fluorescent markers and light-activated cation channels. Experimental procedures involve administration of the viral vectors into animal models. Work practices, procedures, and facilities are appropriate for the planned research.

NIH Guidelines: III-D-4

Training and Facilities: Some lab members need training, and they will be notified to complete training. Inspection of the facilities noted that the biosafety cabinet needs to be certified.

Vote: Approve at BSL1

For: 11 | Absent: 2 | Against: 0 | Conflict of Interest: 0 | Abstained: 0

IBC Meeting Minutes, August 13, 2026



Sophia Onwuzulike returns to the meeting.

Investigator: Chen Zhao

Project Title: Identifying and Characterizing the Signals that Regulating Normal Hematopoietic Stem Cells and Leukemia/Lymphoma Initiating Cells and Their Microenvironment

IBC Protocol: IBC-2020-380

Project Overview, Risk Assessment and Discussion:

This study involves the use of replication incompetent retroviral and lentiviral vectors, which will be packaged into viral particles. These viral vectors will then be used to perform gene editing, knockdown, and overexpression of genes (including reporter genes and genes involved in the regulation of blood cells) in cultured human cell lines and primary cells. The modified cells will be introduced into animal models for further investigation, and these animals 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

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 2 with minor edits

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

Amendments:

Investigator: Afshin Dowlati

Project Title: Precision Medicine for Small Cell Lung Cancer

IBC Protocol: IBC-2021-399

Project Overview, Risk Assessment and Discussion:

The research uses replication-deficient lentiviral and adenoviral viral vectors for overexpression, knockdown, or knockout (CRISPR) of genes encoding reporters and enzymes. The vectors will be used in cell culture systems, including human lung cancer cell lines, and mouse primary lung organoids. The amendment adds an experiment to introduce cells expressing a reporter gene into animal models. Work practices and procedures are consistent with BSL2 standards and appropriate for the planned research.

IBC Meeting Minutes, August 13, 2026



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

Investigator: Xin Qi

Project Title: Investigation of mitochondrial activity using AAV

IBC Protocol: IBC-2020-365

Project Overview, Risk Assessment and Discussion:

This protocol utilizes non-pathogenic, replication-deficient adeno-associated viral (AAV) vectors in animal models. The amendment adds shRNA constructs for delivery via AAV. Use of alpha-synuclein preformed fibrils (PFFs) in animal models was also added. Following administration of AAV or PFFs, animals will be housed in a standard housing room. Decontamination with 1% SDS was specified by the committee. Work practices and procedures are appropriate for the planned research.

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 with minor edits.

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

Ron Conlon leaves the meeting.

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

Notice of Administrative Amendments

IBC #	PI	Title	Amendment
IBC-2025-564	Park	Gene therapy to combat retinitis pigmentosa	Personnel
IBC-2025-551	Jastrzebska	G protein-coupled receptors in retina homeostasis	Personnel
IBC-2024-512	Rollins	5D impulse mapping in the embryonic heart	Personnel

Notice of Terminated Protocols

IBC #	PI	Title
IBC-2023-491	Stamler	A novel nitrosylase that prevents hypoglycemia and mediates insulin resistance
IBC-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

Other Business – October meeting will be moved to Oct 15, 2026 with confirmation of quorum.

Next Meeting: September 10, 2026

Meeting Adjourned: 4:00 PM.