Minutes of the CWRU Institutional Biosafety Committee

IBC of record for the Louis Stokes Cleveland VAMC

Meeting Date: March 12, 2026

Members Present:

Charlie Bark, Scott Becka (alternate VA rep*), Cheryl Cameron, Ronald Conlon, Craig Hodges (Chair), Kenneth Matreyek, Monica Montano (Vice Chair), Sophia Onwuzulike, Reshmi Parameswaran, Alexander Rodriguez-Palacio, Ivy Samuels (VA rep), Aaron Severson, Koen van Besien, Pamela Vanderzalm, Andrew Young

Ex-Officio Members and Guests:

Colleen Karlo, Marissa Wolfe (subject matter expert – animals), Lorrie Rice

Abstained from voting since VA rep was 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 February meeting minutes with the additional, specific changes.
For: 12 | Against: 0 | Conflict of Interest: 0 | Abstained: 1

Aaron Severson arrives.

Safety and Incident Reporting - None

Charles Bark arrives.

Review of Initial Protocols:

Investigator: Shahla Bari
Project Title: Mechanisms of Resistance to Chemo-Immunotherapy (including targeted agents) in advanced Solid Tumors
IBC Protocol: #IBC-2026-571

Project Overview, Risk Assessment and Discussion:
The research involves the introduction of murine cell lines containing a reporter gene into animal models, which will be housed in a standard housing room. The cell lines may already contain the recombinant DNA, or recombinant DNA may be introduced using replication incompetent lentiviral vectors. 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: A few personnel are due for 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: 14 | Against: 0 | Conflict of Interest: 0 | Abstained: 1

Investigator: Sudha Chakrapani
Project Title: Recombinant Protein Expression Using Baculovirus-Insect Cell Systems and Transient/Stable Expression in HEK Cells
IBC Protocol: #IBC-2026-570

Project Overview, Risk Assessment and Discussion:
The research will use a baculovirus expression system and mammalian expression plasmids for expression of reporter genes and affinity tags along with receptors and enzymes of interest. An insect cell line (baculovirus) and human cell line (plasmids) will be used with the expression systems.

NIH Guidelines: III-E

Training and Facilities: The Investigator and laboratory staff have completed training. They will be notified to complete the NIH Recombinant DNA Guidelines training module. 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 | Against: 0 | Conflict of Interest: 0 | Abstained: 1

Review of Continuing Protocols:

Investigator: John Diehl
Project Title: Analysis of cell proliferation and cell death
IBC Protocol: #IBC-2019-341

Project Overview, Risk Assessment and Discussion:
The researchers will use retrovirus, lentivirus, and baculovirus vector systems in cell culture. The retroviral vectors are specific for murine cells, the lentiviral vectors can transduce mammalian cells, and the baculovirus is specific for insect cells. The vectors will be used for overexpression of genes of interest or expression of shRNA to knockdown gene expression. 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 training. They will be notified to complete the NIH Recombinant DNA Guidelines training module. 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 | Against: 0 | Conflict of Interest: 0 | Abstained: 1

Investigator: Alex Gifford
Project Title: 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
IBC Protocol: #IBC-2023-480

Project Overview, Risk Assessment and Discussion:
The study involved delivery of a lipid nanoparticle carrying mRNA via a nebulizer. Respiratory protection will be worn by study staff during the administration of the investigational product. Work practices and procedures are consistent with universal precautions and appropriate for the planned research.

NIH Guidelines: III-C

Training and Facilities: A few personnel are due for retraining. 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 (administration) upon completion of training.
For: 14 | Against: 0 | Conflict of Interest: 0 | Abstained: 1

Koen van Besien leaves the meeting.

Investigator: Mark Jackson
Project Title: Identifying breast cancer genes by validation based insertional mutagenesis (VBIM)
IBC Protocol: #20071201

Project Overview, Risk Assessment and Discussion:
The research will include the use of replication incompetent lentiviral vectors in cell culture (human and murine cell lines) for overexpression of genes, for expression of gene editing components to generate knockouts and to insert a reporter cassette, and expression of shRNA. Lentiviral vectors will also be used for random mutagenesis in cell culture. Stable cell lines may be 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-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: 13 | Against: 0 | Conflict of Interest: 0 | Abstained: 1

Investigator: Alan Levine
Project Title: Ectopic expression of signaling proteins, shRNA to said protein or microRNA
IBC Protocol: #20091201

Project Overview, Risk Assessment and Discussion:

The researchers are using replication incompetent lentiviral vectors for gene overexpression, shRNA inhibition, or gene deletion using CRISPR/Cas in human cells in culture. Work practices, procedures, and facilities are consistent with BSL2 standards and appropriate for the planned research. The use of bleach for disinfection of liquid waste needs to be updated to be consistent with OH EPA regulations.

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

Training and Facilities: Several personnel are due for 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: 13 | Against: 0 | Conflict of Interest: 0 | Abstained: 1

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 study will manufacture CAR-T cells locally using a non-viral gene editing system in T cells obtained from study participants to express the BAFF ligand. Work practices and procedures are consistent with BSL2 standards and appropriate for the planned research.

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

Training and Facilities: Several personnel are due for 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: 12 | Against: 0 | Conflict of Interest: 1 (***Parameswaran***)| Abstained: 1

Investigator: Wen-Cheng Xiong
Project Title: Investigations of Neuromuscular junction regeneration, and the pathological mechanisms of Alzheimer's Disease and Osteoporosis
IBC Protocol: #IBC-2017-275

Project Overview, Risk Assessment and Discussion:

Multiple viral vector systems will be utilized for the research, including replication incompetent lentivirus, AAV, and retrovirus. Rabies virus containing a deletion of the native glycoprotein and pseudotyped with the avian virus envelope protein will also be used. The viral vectors will be used in cell culture as well as in animal models, where animals receiving RG2/3 viral vectors will be housed at ABSL2 for a period of time appropriate to the agent. 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. They will be notified to complete the NIH Recombinant DNA Guidelines training module. Inspection of the facilities noted that a room location needs to be updated in the study application, and the biosafety cabinets need to be certified.

Vote: Approve at BSL2 with minor edits.
For: 13 | Against: 0 | Conflict of Interest: 0 | Abstained: 1

Investigator: Pushpa Pandiyan
Project Title: SARS-Cov2 infections of human cells in vitro and mouse in vivo
IBC Protocol: #IBC- 2021-423

Project Overview, Risk Assessment and Discussion:
The lab is using recombinant strains of SARS-CoV-2 for cell culture and animal experiments. There are detailed descriptions of biosafety measures in the BSL3 and ABSL3 facilities and are 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. They will be notified to complete the NIH Recombinant DNA Guidelines training module. There were no concerns regarding the facilities to accommodate the safety and containment requirements of the proposed experiments.

Vote: Approve at BSL3 upon completion of training
For: 13 | Against: 0 | Conflict of Interest: 0 | Abstained: 1

Investigator: Stephen Carpenter
Project Title: Cloning T cell antigen receptors (TCRs) and RNAi knockdown of human macrophage gene expression to study T cell responses to Mycobacterium tuberculosis infection
IBC Protocol: #IBC- 2024-515

Project Overview, Risk Assessment and Discussion:
The research will use replication incompetent lentiviral vectors for gene expression in cell culture. These cells will be further investigated by infection with recombinant strains of ***Mycobacterium tuberculosis***. Work practices and procedures are consistent with BSL2 and BSL3 standards and appropriate for the planned research. All ***M. tuberculosis*** work will be conducted at BSL3.

NIH Guidelines: III-D-1, III-D3

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

Vote: Approve at BSL3
For: 13 | Against: 0 | Conflict of Interest: 0 | Abstained: 1

Review of Amendments:

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 amendment adds personnel and two new genes to be investigated using replication incompetent lentiviral vectors in cell culture. Work practices, procedures, and facilities are consistent with BSL2 standards and appropriate for the planned research.

NIH Guidelines: NIH Guidelines: III-D-1, III-D3

Training and Facilities: The Investigator and laboratory staff have completed training. Inspection of the facilities noted that the biosafety cabinets need to be certified.

Vote: Approve at BSL2 with minor edits.

For: 13 | Against: 0 | Conflict of Interest: 0 | Abstained: 1

Scott Becka leaves the meeting.

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 adds a new nanoparticle for investigation in animal models. Work practices, procedures, and facilities are consistent with BSL2 standards and appropriate for the planned research.

NIH Guidelines: NIH Guidelines: III-D-4

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 approved with minor edits
For: 13 | Against: 0 | Conflict of Interest: 0 | Abstained: 0

Kenneth Matrayek leaves 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:
The amendment adds two new genes to be investigated using replication incompetent lentiviral vectors in cell culture. Work practices, procedures, and facilities are consistent with BSL2 standards and appropriate for the planned research.

NIH Guidelines: 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 | Against: 0 | Conflict of Interest: 0 | Abstained: 0

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 an experiment involving the introduction of plasmids (capable of integrating into cells) into animal models. The committee discussed the risks associated with administration to the animals and defined safe sharps procedures to mitigate the risks. Work practices, procedures, and facilities are consistent with BSL2 standards and appropriate for the planned research and the animals will be housed at ABSL2 for 7 days.

NIH Guidelines: 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 with an update to the procedures.
For: 12 | 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. The amendment adds a procedure involving the introduction of mRNA into murine cells.

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

Notes to Committee:

Administrative Amendments

IBC #	PI	Title	Amendment
2025-562	Anderson	Anderson Lab Neurologic Disease Research	Update personnel
2021-418	Burberberry	Modeling the diseases Amyotrophic lateral sclerosis and Frontotemporal dementia in human and mouse systems	Adding exempt experiment (ASOs)
2018-295	Rietsch	Type III secretion effector function	Update personnel

Notices of Closed Protocols/Terminations

IBC #	PI	Title
20090701	Gupta	Epigenetics changes by green tea in human prostate cancer lines

Next Meeting: April 9, 2026

Meeting Adjourned: 4:15 PM.