Minutes of the CWRU Institutional Biosafety Committee

IBC of record for the Louis Stokes Cleveland VAMC

Meeting Date: December 11, 2025

Members Present:

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

Ex-Officio Members and Guests:

Colleen Karlo, Lorrie Rice, Jennifer Berendt

Abstained from voting since VA rep was present.

Meeting Convened: 3:03 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 November meeting minutes with the additional, specific changes.
For: 16 | Absent: 0 | Against: 0 | Conflict of Interest: 0 | Abstained: 1

Safety and Incident Reporting - None

Review of New Protocols:

Investigator: Jeffrey Schelling

Project Title: Role of FATP2 in Regulating Alpha-Cell-Derived GLP-1 Synthesis and Secretion: Implications for Type 2 Diabetes Therapy
IBC Protocol: #IBC-2025-565

Project Overview, Risk Assessment and Discussion:
The research will utilize replication incompetent lentiviral vector system to generate a gene knockout in a murine cell line. 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 with minor edits.
For: 16 | Absent: 0 | Against: 0 | Conflict of Interest: 0 | Abstained: 1

Investigator: Paul Park
Project Title: Gene therapy to combat retinitis pigmentosa
IBC Protocol: #IBC-2025-564

Project Overview, Risk Assessment and Discussion:
The research involves gene transfer into animals using a lipid nanoparticle to deliver cDNA or genomic DNA for gene expression. Work practices, procedures, and facilities are consistent with BSL1 containment, and safe sharps practices and PPE are described. Animals will be housed in a standard housing room.

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 BSL1 with minor edits.
For: 16 | Absent: 0 | Against: 0 | Conflict of Interest: 0 | Abstained: 1

Investigator: Amar Desai
Project Title: Evaluation of small molecule inhibitors on growth of luciferase tagged human xenografts in NSG mice
IBC Protocol: #IBC-2025-566

Project Overview, Risk Assessment and Discussion:
The research will utilize existing human cancer cells expressing a reporter gene. The cells will be introduced into animal models, and the animals will be housed in a standard housing room. Work practices, procedures, and facilities for cell work and injections are consistent with BSL2 containment. The committee recommends the use of disposable needles and syringes for the injections, allowing for immediate disposal into a biohazardous sharps container.

NIH Guidelines: III-D-4

Training and Facilities: The Investigator and laboratory staff have completed basic lab safety and biosafety training. Upon inspection of the facilities, the biosafety officer noted that the room number referenced in the study application for the cell culture work needs to be corrected.

Vote: Approve at BSL2 with minor edits.
For: 16 | Absent: 0 | Against: 0 | Conflict of Interest: 0 | Abstained: 1

Investigator: Matthew Anderson
Project Title: Anderson Lab Neurologic Disease Research
IBC Protocol: #IBC-2025-562

Project Overview, Risk Assessment and Discussion:
The lab will utilize replication incompetent viral vector systems to achieve gene expression, expression of CRISPR editing components to generate gene point mutations or deletions, or delivery of siRNA for gene knockdown to investigate neurological diseases. A lentiviral vector system will be used to transduce human cells in culture, and AAV will be used for delivery of siRNA or genes of interest in animal models, with animals housed in a standard housing room. A non-K-12 strain of E. coli will be utilized for protein production of membrane proteins. Work practices, procedures, and facilities are consistent with BSL2 containment and appropriate for the planned research.

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

Training and Facilities: One individual needs training, and they will be notified to complete training. Inspection of the facilities noted that signage is needed for the tissue culture room.

Vote: Approve at BSL2 with minor edits.
For: 16 | Absent: 0 | Against: 0 | Conflict of Interest: 0 | Abstained: 1

Reshmi Parameswaran moved to the waiting room.

Investigator: Radhika Atit
Project Title: CAR-T therapy for preventing lipodystrophy and skin fibrosis
IBC Protocol: #IBC-2025-567

Project Overview, Risk Assessment and Discussion:
The research involves the introduction of murine T cells expressing a chimeric antigen into animal models. Work practices, procedures, and facilities are consistent with BSL1 containment, and safe sharps practices and PPE are described. Animals containing the murine CAR-T cells will be housed in a standard housing room.

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 BSL1
For: 15 | Absent: 0 | Against: 0 | Conflict of Interest: 1 | Abstained: 1

Reshmi Parameswaran returns to the meeting.

Review of Continuing Protocols:

Investigator: George Yendewa
Project Title: 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.
IBC Protocol: #IBC-2024-511

Project Overview, Risk Assessment and Discussion:
The study involves two vaccines, a prime adenovirus vaccine and a boost modified vaccinia Ankara vaccine in combination with neutralizing antibodies. Work practices, procedures, and facilities are consistent with BSL2 containment, and safe sharps practices and PPE are described.

NIH Guidelines: III-C

Training and Facilities: The Investigator and laboratory staff have completed 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: 16 | Absent: 0 | Against: 0 | Conflict of Interest: 0 | Abstained: 1

Investigator: Susann Brady-Kalnay
Project Title: Expression of PTPu signaling pathway proteins by a retroviral vector and lentiviruses
IBC Protocol: #20010510

Project Overview, Risk Assessment and Discussion:
The research involves replication incompetent lentivirus or retrovirus vector systems. The viruses will be used to transduce human and murine cancer cell lines in culture for gene expression, or expression of shRNA to investigate signaling pathways. 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: 16 | Absent: 0 | Against: 0 | Conflict of Interest: 0 | Abstained: 1

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 research will investigate delivery systems in animal models: nanoparticles, replication deficient AAV, plasmids, and viral-like particles will be used for delivery and expression of fluorescent reporter genes, gene editing components, and recombinase enzyme. Work practices, procedures, and facilities are consistent with BSL2 standards, and safe sharps practices and PPE are described. Researchers will wear a respirator for procedures with the potential to generate aerosols and cannot be conducted within a biosafety cabinet. Animals will be housed in a standard housing room.

NIH Guidelines: III-D-4

Training and Facilities: There is laboratory staff due for safety retraining, 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 upon completion of training
For: 16 | Absent: 0 | Against: 0 | Conflict of Interest: 0 | Abstained: 1

Investigator: Xin Qi
Project Title: Regulation of mitochondrial proteins in models of Huntington's disease
IBC Protocol: #IBC-2017-258

Project Overview, Risk Assessment and Discussion:
The research will use replication incompetent lentiviral vectors for expression of fluorescent marker genes, genes of interest or si/shRNA to knockdown genes in human or murine cells in 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

Training and Facilities: One individual needs training, and they will be notified to complete training. Upon inspection of the facilities, the biosafety officer noted that the room number referenced in the study application for the cell culture work needs to be corrected.

Vote: Approve at BSL2 with minor edits and completion of training.
For: 16 | Absent: 0 | Against: 0 | Conflict of Interest: 0 | Abstained: 1

Investigator: Allison Kraus

Project Title: Ultrasensitive assays for protein aggregates
IBC Protocol: #IBC-2019-347

Project Overview, Risk Assessment and Discussion:
The research will generate recombinant proteins. Expression plasmids encoding proteins of interest are transformed into non-K-12 strain of E. coli for expression and purification. Work practices, procedures, and facilities are consistent with BSL2 standards and appropriate for the planned research as some of the transgenes are from a RG3 agent.

NIH Guidelines: III-D-2

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

Investigator: Sanjay Gupta
Project Title: Epigenetics changes by green tea (EGCG) in human prostate cancer lines
IBC Protocol: #IBC- 20090701

Project Overview, Risk Assessment and Discussion:
The lab is investigating genes of interest using replication incompetent lentiviral vectors for shRNA-based knockdowns and cDNA overexpression in human cell lines in culture. CRISPR/Cas9 experiments for gene knockouts will be done through transfection of shRNA and Cas9 enzyme into human 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: One individual needs 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: 16 | Absent: 0 | Against: 0 | Conflict of Interest: 0 | Abstained: 1

Review of Amendments:

Investigator: Stephanie Langel
Project Title: Maternal immunization for generation of potently neutralizing antibodies in breast milk
IBC Protocol: #IBC- 2023-471

Project Overview, Risk Assessment and Discussion:
The research involves administration of an adenovirus vaccine to animal models. The amendment revises the procedure for delivering the vaccine to the animals. The updated procedure will occur within a biosafety cabinet and work practices and procedures are consistent with BSL2 standards and appropriate for the planned research, and animals are housed at ABSL2 for 72 hrs after administration.

NIH Guidelines: III-D-1, 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
For: 16 | Absent: 0 | Against: 0 | Conflict of Interest: 0 | Abstained: 1

Investigator: Daniel Simon
Project Title: Tumorigenicity study of human Foxp1 gene truncate isoforms
IBC Protocol: #IBC-2018-314

Project Overview, Risk Assessment and Discussion:
The amendment to the protocol adds the use of existing murine cell lines expressing luciferase and introduced into animal models. Work practices, procedures, and facilities are consistent with BSL2 containment, and safe sharps practices and PPE are described. Animals will be housed in a standard housing room following administration of cells.

NIH Guidelines: 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: 16 | Absent: 0 | Against: 0 | Conflict of Interest: 0 | Abstained: 1

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

NIH Guidelines: III-E

Vote: Approve at BSL1
For: 15 | Absent: 0 | Against: 0 | Conflict of Interest: 1 | Abstained: 1

Ron Conlon returns to the meeting.

Notice of Administrative Amendments

IBC #	PI	Title	Amendment
2022-458	Metheny	Phase 1 Study of BAFF CAR-T cells (LMY-920) for Treatment of Relapsed or Refractory Myeloma	Update personnel, updated clinical protocol.
2025-560	Gan	Elucidating Novel PRMT Regulatory Mechanisms And Their Roles in Tumorigenesis	Update personnel

Notice of Terminated Protocols

IBC #	PI	Title
2023-472	Hodges	CFTR correction in Cystic Fibrosis through HSV-1 delivery
2023-500	Chiec/Dowlati	MRK1523: A Phase 3, Randomized, Double-blind, Placebo- and Active-Comparator- Controlled Clinical Study of Adjuvant V940 (mRNA-4157) Plus Pembrolizumab Versus Adjuvant Placebo Plus Pembrolizumab in Participants With Resected Stage II, IIIA, IIIB (N2) Non-small Cell Lung Cancer

Next Meeting: January 15, 2026

Meeting Adjourned: 4:02 PM.